CLINICAL LABORATORIES

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

MAY 2, 1991

Serial No. 102–67

Printed for the use of the Committee on Energy and Commerce

U.S. GOVERNMENT PRINTING OFFICE
51-623 WASHINGTON : 1992

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-037353-0

COMMITTEE ON ENERGY AND COMMERCE

JOHN D. DINGELL, Michigan, *Chairman*

JAMES H. SCHEUER, New York
HENRY A. WAXMAN, California
PHILIP R. SHARP, Indiana
EDWARD J. MARKEY, Massachusetts
AL SWIFT, Washington
CARDISS COLLINS, Illinois
MIKE SYNAR, Oklahoma
W.J. "BILLY" TAUZIN, Louisiana
RON WYDEN, Oregon
RALPH M. HALL, Texas
DENNIS E. ECKART, Ohio
BILL RICHARDSON, New Mexico
JIM SLATTERY, Kansas
GERRY SIKORSKI, Minnesota
JOHN BRYANT, Texas
RICK BOUCHER, Virginia
JIM COOPER, Tennessee
TERRY L. BRUCE, Illinois
J. ROY ROWLAND, Georgia
THOMAS J. MANTON, New York
EDOLPHUS TOWNS, New York
C. THOMAS McMILLEN, Maryland
GERRY E. STUDDS, Massachusetts
PETER H. KOSTMAYER, Pennsylvania
RICHARD H. LEHMAN, California
CLAUDE HARRIS, Alabama

NORMAN F. LENT, New York
CARLOS J. MOORHEAD, California
MATTHEW J. RINALDO, New Jersey
WILLIAM E. DANNEMEYER, California
DON RITTER, Pennsylvania
THOMAS J. BLILEY, Jr., Virginia
JACK FIELDS, Texas
MICHAEL G. OXLEY, Ohio
MICHAEL BILIRAKIS, Florida
DAN SCHAEFER, Colorado
JOE BARTON, Texas
SONNY CALLAHAN, Alabama
ALEX McMILLAN, North Carolina
J. DENNIS HASTERT, Illinois
CLYDE C. HOLLOWAY, Louisiana
FRED UPTON, Michigan

John S. Orlando, *Chief of Staff*
John M. Clough, Jr., *Staff Director*
Margaret A. Durbin, *Minority Chief Counsel/Staff Director*

Subcommittee on Oversight and Investigations

JOHN D. DINGELL, Michigan, *Chairman*
J. ROY ROWLAND, Georgia
RON WYDEN, Oregon
DENNIS E. ECKART, Ohio
JIM SLATTERY, Kansas
GERRY SIKORSKI, Minnesota
JOHN BRYANT, Texas

THOMAS J. BLILEY, Jr., Virginia
NORMAN F. LENT, New York
DAN SCHAEFER, Colorado
FRED UPTON, Michigan

Reid P.F. Stuntz, *Staff Director/Chief Counsel*
Stephen F. Sims, *Deputy Staff Director*
D.Ann Murphy, *Special Assistant*
Stanley Edinger, *Special Assistant*
John J. Hambel, *Minority Counsel*

Public Laws: 102nd Congress/1st Session/House Hearings/1991 Pt. [1]

CONTENTS

Page

Testimony of:

- Allen-Jones, Bette C., internist, Westfield, NJ 43
- DeBoy, Jack, Assistant Director of Laboratories Administration, Maryland Department of Health and Mental Hygiene 45
- Dickerman, Herbert W., director, Wadsworth Center, New York State Department of Health 147
- Kroger, J. Stephen, chief executive officer, Commission on Office Laboratory Assessment 173
- MacRae, James B., Jr., Acting Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget 93
- Magazine, Alan H., president, Health Industry Manufacturers Association 171
- Roper, William L., Director, Centers for Disease Control 78
- Scalettar, Raymond, member, board of trustees, American Medical Association 156
- Wagner, Loyd, president, College of American Pathologists 210
- Wilensky, Gail R., Administrator, Health Care Financing Administration. 63

Material submitted for the record by:

- American Association of Bioanalysts: Letter and attachments from Mark S. Birenbaum, associate administrator, to Chairman Dingell, May 1, 1991 240
- National Association for Home Care, letter and statement 258

- Oversight and Investigations Subcommittee:

  - Affidavit of Metta Cogburn 44
  - Memorandum and supporting documents dated May 1, 1991 4

CLINICAL LABORATORIES

THURSDAY, MAY 2, 1991

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2123, Rayburn House Office Building, Hon. John D. Dingell (chairman) presiding.

Mr. Dingell. Good morning. The subcommittee will come to order.

The hearing today is the first in a series in which the subcommittee will examine the adequacy of the Health Care Financing Administration's efforts to implement the Clinical Laboratory Improvement Amendments of 1988, which was originated by this subcommittee and this committee.

The Committee on Energy and Commerce and ultimately the Congress itself passed CLIA '88 when in-depth investigations by the Subcommittee on Regulation and Business Opportunities of the Subcommittee on Small Business, chaired very ably by Mr. Wyden, and this subcommittee as well as others, discovered and identified an alarming trend of laboratory errors that are putting patients at significant risk. We had sought to revamp laboratory regulation to bring public policy into line with dramatic changes in the medical testing industry that had occurred in the 22 years since the passage of the first CLIA in 1967.

Implementation of CLIA '88, therefore, is of particular interest to this committee and to this subcommittee. Unfortunately, the testimony that we will hear today from the private sector and from State officials suggests that little progress has been made since Congress took decisive action some 2½ years ago.

Today, not one component of that critical legislation's regulatory activities is in place. Indeed, many of the questions that we will be asking today are the same questions that were asked by my colleagues and I back in 1988.

We recognize, of course, that the task before the Health Care Financing Administration is a challenging one, and we recognize that laboratory regulation is a complex technical proposition. We also recognize that there are dramatically different views on how to implement the regulations.

Nevertheless, there are a number of incontrovertible facts. The subcommittee is painfully aware that there is a significant public threat from inaccurate laboratory testing. In fact, the 1988 committee report on the Act itself identified the following problems:

One, a seriously flawed system for assuring compliance and also an inadequate system for enforcement of Federal standards.

Two, a total absence of regulations for tens of thousands of laboratories and diminished or duplicative regulation of many more.

Three, an ineffective proficiency testing system for evaluating the performance of laboratories.

Four, an inadequate system for overseeing screening for cervical cancer.

And five, a system fraught with inherent conflicts of interest, which in some instances compromise the quality of testing and ultimately patient care.

As the subcommittee convenes to consider these matters, not one of the problems has been adequately rectified. Continuing to put patients at serious risk causes unnecessary suffering, and it causes significant expense. The taxpayer finds himself having to come up with enormous amounts of money, because inaccurate tests mean more unnecessary tests and also higher costs. Americans pay over $20 billion each year for laboratory tests, 40 percent of it funded by Medicare or Medicaid. So there is a clear benefit to reducing the costs of those tests whenever possible.

There are five major areas of concern: First, information on the problem and on possible solutions remains sparse. While HCFA has initiated four proposed regulations to implement CLIA '88, it has not completed one of the studies that were to have been the basis for regulations. That is a curious event. HCFA has not even surveyed or registered laboratories to determine the basic questions of where testing is being done and who is doing it or, indeed, how it's being done. Their estimates of the number of laboratories subject to regulation and the cost of regulating them are used frequently, but we wonder what is the basis for those projections, since no surveys have been completed.

Second, the delay in the regulations needed to provide the public with more protection is troubling. Many States have delayed revising their own regulations, waiting instead to see what HCFA will ultimately do. Further, physicians who might otherwise have voluntarily participated in an accreditation program have taken a wait-and-see attitude, and I think wisely so. In short, HCFA's dramatic bureaucratic paralysis seems to be spreading throughout the entirety of the industry.

Third, the workability of the proposed regulations is suspect. According to many physicians and other health care practitioners, the four regulations actually contradict each other. Individual regulations—such as personnel requirements, for example—were based on little or no data on the availability of the necessary personnel. There is still no consensus on how to evaluate the performance of many tests, and finally there are serious doubts about whether enough samples exist or can be made in the near future to evaluate laboratories' performance.

Fourth, equally alarming is the possibility that a major component of CLIA '88, namely the regulation of physician office laboratories, may be ignored through a backdoor method of manipulating the waiver provision of the Act. It is true that CLIA '88 does provide a method by which a laboratory may obtain a waiver from regulation if its tests, and I quote, "are simple laboratory examinations or procedures which, as determined by the Secretary, have an insignificant risk of erroneous result," close quote. But despite the Centers for Disease Control's first recommendation that no test is insignificant if done incorrectly, HCFA has developed a list of waivers that includes some 28 tests.

Fifth, the Office of Management and Budget's written comments to HCFA's official record raise serious questions about the scope of regulations, specifically highlighting the costs of regulating physician office laboratories. I am very concerned that these laboratories may again escape regulation in toto. That is not what our investigations found necessary to protect the public, and it is clearly not the intent of the Act itself.

I am pleased to have representatives from HCFA, CDC, and OMB here to testify on these matters. The subcommittee will be working with HCFA in the coming months to see to it that the Act is properly implemented and that it is done so in accordance with the letter and the spirit of the law. I am also particularly pleased that we have today witnesses from the medical communities, the States, and the equipment manufacturers here with us. In the light of the uncertain timetable and the status of HCFA's regulations, I believe that it is crucial that we commence working in partnership to develop much more aggressive self-policing initiatives.

Voluntary efforts are a critical component in an environment of increasingly scarce health care dollars and a regulatory system that is already severely taxed. Ongoing oversight of these initiatives, of course, will be necessary to provide for public accountability and credibility to these programs.

As I stated at the outset, this is the first of the subcommittee's hearings on the Department's implementation of CLIA '88. We will be having other hearings. We hope to be able to work constructively with all of the persons involved to develop policies that truly protect the public. I intend to see to it that with or without the cooperation that we look forward to from the community, that this is done. I do look forward to the cooperation of all parties and look forward to the testimony today.

[Testimony resumes on p. 40.]

[The following subcommittee memorandum and supporting documents were submitted:]

ONE HUNDRED SECOND CONGRESS

JOHN D DINGELL, MICHIGAN, CHAIRMAN

J. ROY ROWLAND GEORGIA
RON WYDEN, OREGON
DENNIS E ECKART, OHIO
JIM SLATTERY KANSAS
GERRY SIKORSKI, MINNESOTA
JOHN BRYANT, TEXAS

THOMAS J BLILEY, JR., VIRGINIA
NORMAN F LENT, NEW YORK
DAN SCHAEFER, COLORADO
FRED UPTON, MICHIGAN

REID P.F. STUNTZ, STAFF DIRECTOR/CHIEF COUNSEL
STEPHEN F. SIMS DEPUTY STAFF DIRECTOR

ROOM 2323
RAYBURN HOUSE OFFICE BUILDING
PHONE (202) 225-4441

U.S. House of Representatives
Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce
Washington, DC 20515

MEMORANDUM

DATE: May 1, 1991

TO: Members, Subcommittee on Oversight and Investigations

FROM: The Honorable John D. Dingell, Chairman

RE: May 2, 1991 Hearing on Adequacy of Efforts to Implement the Clinical Laboratory Improvement Amendments of 1988

I. Introduction

In a public hearing tomorrow, May 2, 1991, the Subcommittee will inquire into the adequacy of efforts to implement the Clinical Laboratory Improvement Amendments of 1988. Witnesses from the Executive Branch, state health departments, and the private sector will testify. (A list of witnesses, with expected areas of testimony, is attached.) The Subcommittee will hear that more expeditious, and more expert, action on the implementing regulations and associated studies is required to meet Congressional mandates.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) was signed into law on October 31, 1988, after numerous Congressional hearings -- many conducted by the Energy and Commerce Committee. Those in-depth investigations identified serious deficiencies in existing laboratory regulations, specifically that accurate, reliable medical tests were not being assured by the existing system. As stated in the Committee report: "When tests are inaccurate or unreliable, the consequences are improper treatment, unnecessary mental and physical anguish for patients and higher health care costs." By bipartisan votes, the Congress agreed that a variety of disturbing practices was clearly in evidence and that the regulatory system itself was in need of reform.

Unfortunately, despite Congressionally-mandated deadlines for speedy implementation of more protective laboratory regulations, nearly two and one half years have passed and patients are no more assured of accurate testing than before. CLIA 88 regulations are not in effect. Further, the government knows little more about the accuracy of the testing being done, where it's being done and who is doing it.

II. Status of Regulations

The current status of the regulations appears uncertain at best. To date, the Health Care Financing Administration (HCFA) has proposed a set of four regulations, all of which have received widespread criticism from virtually all segments of the regulated population, private sector laboratory accrediting bodies and state public health officials. HCFA has been accused of developing the proposed regulations in a bureaucratic vacuum, including the refusal to meet with any of the affected parties at any time since the passage of the Act in 1988. Because HCFA does not conduct public hearings, as do the majority of other government regulatory agencies, HCFA's failure to take advantage of available expertise from the private sector and state regulatory officials is a particularly disturbing omission.

Subcommittee staff has been informed by HCFA's Director of Institutional and Ambulatory Services, who is directly responsible for the regulations, that HCFA staff is currently planning a "major rewrite" of the proposed regulations. According to numerous letters to HCFA and meetings between Subcommittee staff and outside parties, HCFA has received approximately 60,000 written comments on the regulations, but apparently had no direct interaction with experts in the laboratory field. As described, this situation raises serious questions about how or whether HCFA -- and ultimately the Department itself -- can implement CLIA 88 effectively to ensure (1) accurate and reliable tests, (2) ongoing access to care and (3) affordable testing.

In addition, while the Office of Management and Budget (OMB) cleared the four proposed CLIA 88 regulations for publication, it subsequently published formal comments for the HCFA's public record. These comments took issue not only with specific elements of the regulations but with the overall regulatory framework. If adopted, OMB's position could unjustifiably limit the number of laboratories to be regulated. OMB's interference with a variety of rulemakings has been the subject of this Subcommittee's investigations in the past. The extent and nature of its role in the evolution of the CLIA 88 regulations and their final form will continue to be of interest to the Subcommittee.

OMB's comments suggested that the proposed regulations, "may not be consistent with the Administration's objectives in improving our nation's health care delivery systems." In addition, the President's FY 1992 budget targeted CLIA -- and specifically the regulations covering physician office laboratories -- for review under the heading of "reforming regulation and managing risk-reduction sensibly." But, the Energy and Commerce Committee's bipartisan report on CLIA 88 evidenced the intention to directly regulate physician office laboratories because of "the Committee having received evidence of substandard quality in many physician office laboratories." When combined with OMB's comments, the President's Budget statement is alarming in that it suggests a possible attempt by OMB to tamper with this very intent.

For its part, the private sector has expressed widely divergent opinions on the proposed regulations. These concerns are principally directed toward six specific categories: (1) personnel requirements; (2) tests not subject to regulation; (3) degree of regulation for different types of laboratories; (4) proposed fees to be collected from laboratory operators; (5) conditions for evaluating and approving existing state and private sector accrediting programs; and (6) enforcement and inspection provisions. There are reasons for concern in many of these areas, and they will be explored.

III. Status of Mandated Studies

CLIA 88 also required that the Department of Health and Human Services (the Department) conduct five studies to fill in significant gaps in knowledge required to aid in the development of more protective, workable regulations. Those studies have not been completed. In fact, the Centers for Disease Control (CDC) recently informed the Subcommittee that even the study designs will not be completed for nearly another year -- with the final results unavailable for another five years.

Despite the lack of evidence on the number of laboratories, where they are, and who is testing, claims of high regulatory costs and predictions of laboratory closings have been advanced repeatedly. For example, a Health Industry Manufacturers Association's sponsored study suggested that the implementation of the CLIA 88 regulations as proposed could cost the health care system as much as $4 billion each year. This number is now frequently used by the industry and practitioners alike as fact to argue for additional -- if not complete -- exemption from any type of regulation. Independent, federal, and state health care officials have not completed comprehensive studies to support such cost figures. Nor do they have documentation to support any cost estimates of the proposed regulations or to determine whether the proposed regulations will prompt countless laboratories simply to close their doors.

In a similar manner, although legitimate questions have also been raised about whether the proposed regulations could limit many patients access to medical testing, a recent Office of Technology Assessment (OTA) study entitled "Health Care in Rural America" stated that "assessing the availability of allied health professionals (AHPs) is hindered by the lack of national data, including the rural/urban distribution of AHPs, which prevents an accurate determination of the shortage." In fact, the OTA conclusions in that regard were limited to anecdotal evidence and small-area studies suggesting that some rural facilities are already suffering critical shortages of laboratory personnel. No comprehensive assessment of shortages has been made.

IV. Need for More Expeditious, and More Expert, Action

A great deal is at stake. Patients' well-being is crucial, but we cannot ignore the potential for negative impacts on access to care and increased costs of that care. However, safer and more reliable test results and diagnoses based on them may not be ensured. In 1988 alone, Americans spent $20 to $25 billion on between four and six billion laboratory tests. Fueled by technological advancements and changes in the federal government's efforts to save increasingly scarce health care dollars by revamping reimbursement policies, testing ranging from blood workups to PAP smears and cholesterol screening has moved from laboratories that are regulated, and therefore subject to some degree of public accountability, to unregulated laboratories in nursing homes, mobile laboratories and even shopping centers.

Unfortunately, over two years after we first explored these critical public health issues, the Congress is left with as many questions as answers. Indeed, some six years ago Congress passed the 1985 Omnibus Budget Reconciliation Act, directing the Department to gather additional data on physician office laboratory testing and to develop model regulatory standards for them. The Subcommittee's hearing on Thursday is but the first in a series to evaluate delays in HCFA's implementation of the regulations, the manner in which they were developed and the status of their implementation. We will also examine how effectively the Department has coordinated the activities and shared responsibilities of HCFA, CDC and the Food and Drug Administration.

To be sure, the Subcommittee will continue to monitor the progress of the Department and to urge more aggressive actions. Given the uncertain status of the regulations' implementation and their content -- not to mention the potential for legal challenges -- other options to fully implemented regulations must be considered in the interim. For example, the Subcommittee staff is exploring with HCFA and the Department the feasibility and benefit of incrementally implementing -- even on a provisional basis -- specific elements of the regulations. The benefits would be twofold: enhanced knowledge of what is actually going in the testing arena and progress toward ensuring more reliable and safer testing results. Indeed, CLIA 88 itself specifically allowed for incrementally imposing various provisions of the statute, including the standards, sanctions and personnel components.

Also, the Subcommittee staff is discussing with practitioners, accrediting organizations and equipment manufacturers efforts to develop and promote more aggressive voluntary self-policing efforts. Those activities could enhance performance in currently unregulated laboratories and generate important information upon which the Department can base more protective yet practical final regulations. The Subcommittee expects to review any self-policing initiatives to assess their effectiveness and the Department's use of the information generated.

Finally, a broader look at HCFA's oversight of (1) the nearly $200 billion Medicaid and Medicare programs at both the federal and state levels (all taxpayer money) and (2) the quality of care provided by physicians and other health care professionals will likely be necessary, including the role of OMB in the Department's rulemaking and enforcement efforts.

Attachment

ATTACHMENT

WITNESS LIST AND AREAS OF TESTIMONY

PANEL I

Dr. Betty Allen-Jones
Internist and Emergency Room Physician
Brooklyn, New York

Dr. Allen-Jones and her unborn child underwent testing for sickle cell. Two different laboratories performing the tests did the tests incorrectly. They all suggested that the child had a serious form of sickle cell. After 18 months of uncertainty and fear, the family learned that they were not afflicted with a serious form of sickle cell -- a disease which can be and often is fatal. Dr. Allen-Jones, both in her capacity as a mother and as a practicing physician, will address her concerns about exempting the sickle cell test from regulation.

Dr. Jack DeBoy
Chief
Maryland Division of Laboratory Licensure,
Certification and Training

Dr. DeBoy's testimony will focus on a recent incident at a Maryland nursing home in which three elderly diabetes patients died as a result of misread glucose tests performed by nurses in the facility. Because of these erroneous test results, the patients were administered incorrect dosages of insulin. The test device used is one that is commonly used in physician office laboratories as well as by patients themselves in their own homes. It is also one of the specific tests that many practitioners and the OMB have suggested be waived.

PANEL II

Dr. Gail Wilensky
Administrator
Health Care Financing Administration (HCFA)

Dr. Wilensky will describe HCFA's actions in developing the proposed regulations, the process being utilized to assess the more than 60,000 public comments on the regulations and to develop final regulations, and the timetable for issuance and implementation of the final regulations. Additionally, Dr. Wilensky will be asked to respond to questions regarding other regulatory and voluntary actions to bring laboratories under tighter regulation as the final regulations are developed and as the regulations are phased in.

Dr. William Roper
Director
Centers for Disease Control (CDC)

Dr. Roper, who was HCFA Administrator during the 1988 investigations and subsequent passage of CLIA 88, will testify on CDC's role in the development of the proposed regulations and of the studies mandated by the legislation. CDC's anticipated ongoing responsibilities to provide resources and technical advice on the CLIA 88 standards and their updating will also be addressed by Dr. Roper.

Mr. James B. MacRae, Jr.
Acting Administrator and Deputy Administrator of the
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)

Mr. MacRae's testimony -- as well questions to him -- will focus on the methodology utilized by OMB in reviewing the proposed regulations, any alterations required by OMB prior to their publication, and OMB's subsequent formal comments to the record on HCFA's regulations. Further, Mr. MacRae will be asked to detail OMB's contacts with the private sector and other federal or state officials regarding the CLIA 88 regulations.

PANEL III

Dr. Herbert W. Dickerman, M.D., Ph.D.
Director
Wadsworth Center for Laboratories and Research
New York State Department of Health

New York State for many years has operated one of the most aggressive laboratory regulatory programs in the country. Dr. Dickerman's testimony will describe both that state program and the problems caused by the federal government's delay in implementing CLIA 88. He will discuss the consequences of HCFA's failure to recognize New York State's existing program and the ongoing problems of unreliable and unsafe laboratory testing in a wide range of laboratory settings.

PANEL IV

Dr. Raymond Scalettar
Member of the Board of Trustees
American Medical Association (AMA)

Dr. Scalettar will direct the bulk of his testimony to AMA's position on the proposed regulations and on its assessment of the proposed regulations' impacts on laboratory accuracy, access to care and cost of care. In addition, Dr. Scalettar will describe for the Subcommittee AMA's plans to conduct a survey of physician office laboratories in conjunction with the Health Industry Manufacturers Association and the American Hospital Association. Increased efforts to encourage voluntary participation in accrediting programs and continuing education in laboratory services will also be the subject of Dr. Scalettar's testimony.

Mr. Alan H. Magazine
President
Health Industry Manufacturers Association (HIMA)

Mr. Magazine will testify on HIMA's position on the proposed regulations, on HIMA's concerns regarding the allegedly closed process by which HCFA developed the regulations and the implications for the final regulations. He will also discuss HIMA members' existing training and monitoring programs for different laboratory equipment and the possibility for enhanced voluntary initiatives to improve the type, extent and frequency of training and thereby the quality of testing as well.

Dr. J. Stephen Kroger
Chief Executive Officer
Commission on Office Laboratory Assessment (COLA)

Dr. Kroger is the Director of the only accrediting organization designed for physician office laboratories. His description of COLA's inspection and proficiency testing programs in some 1,300 physician office laboratories will be of particular value to the Subcommittee in asssessing the efficacy and effectiveness of the proposed regulations. He will also explore the feasibility of more aggressive initiatives from the medical community to encourage additional participation in voluntary accreditation efforts.

PANEL V

Dr. Loyd Wagner
President
College of American Pathologists (CAP)

Dr. Wagner will provide testimony based on CAP's extensive data base. Specifically, he will explain trends in laboratory testing practices and settings, as well as in the reliability of a wide range of tests conducted in different types of laboratories. He will also discuss the College's ability to expand to cover additional clinical laboratories. CAP's evaluation of the proposed regulations and their implications for quality of testing, access to testing and cost of testing will be presented.

Baltimore Sun 2/21/91
p.B1

Four deaths tied to lapses in care at nursing home

By Jonathan Bor

Maryland health authorities have linked the deaths of four patients at the Seton Hill Manor nursing home to lapses in medical and nursing care and have ruled that the home may no longer admit new patients until it dramatically improves conditions.

State inspectors, who toured the facility from Jan. 22 through Feb. 4 and combed through patient records, reported that three tube-fed patients died after their diabetes was improperly managed.

Another patient, an elderly woman with Alzheimer's disease, died a day after becoming entangled in protective straps that were designed to keep her from hurting herself.

Besides banning admissions, the health department ruled that Seton Hill Manor will stop receiving Medicaid reimbursements on March 16. However, lawyers for the home plan to file an appeal — an action that would keep the money flowing for another 120 days while the appeal is being heard. The admissions ban was effective Feb. 8.

The nursing home, at 501 W. Franklin St. in downtown Baltimore, received $7.5 million in Medicaid reimbursements last year — making it one of the largest recipients of Medicaid money in the state's nursing home industry. Licensed for 360 beds, it is the size of some hospitals and ranks as the second-largest nursing home in Maryland.

Seton Hill won accolades in 1985 when it became one of the first nursing homes in the nation, and the first in Maryland, to accept AIDS patients. It now cares for 20 patients with acquired immune deficiency syndrome but plans to expand its AIDS service to accommodate as many as 50 within a month or two.

None of the criticisms leveled at Seton Hill Manor concerned the care of AIDS patients. But the state's acting health secretary, Nelson J. Sabatini, noted widespread problems in the care of elderly patients and said in a letter that "a continued pattern of violations limit the facility's capacity to furnish an adequate level of care."

> *“We have a lot of tube-fed insulin-dependent patients, and at some point it probably got away from us. We need to develop a whole new nursing concept.”*
>
> **LORRAINE RAFFEL**
> **Nursing home owner**

Lorraine Raffel, who owns the home, said she plans to correct the deficiencies within the next few weeks — in time to satisfy inspectors when they return for another survey. She said she has hired a Philadelphia-based consulting firm to help solve its problems, and has hired new nursing managers to overhaul its delivery of care to patients.

Recently, she installed her son, Bruce Raffel, as administrator.

"I think that in nursing, we're seeing many sicker patients than we were ever seeing before," Mrs. Raffel said. "We have a lot of tube-fed insulin-dependent [diabetic] patients, and at some point it probably got away from us. We need to develop a whole new nursing concept."

Seton Hill's troubles did not emerge suddenly.

The home failed the last four annual inspections, according to Mr. Sabatini, but managed to stave off penalties by correcting its problems within a mandated timetable.

Then, after a troublesome inspection last November, Mr. Sabatini warned that he would take action against Seton Hill unless inspectors planning a return visit found substantial improvements. But when they returned last month, they uncovered a host of problems that occurred since the warning — prob-

See DEATHS, 6B, Col. 1

4 nursing home deaths tied to lapses in care

DEATHS, from 1B

lems itemized later in a 62-page report that was made public yesterday. Of the three patients whose diabetes was mismanaged, two died after they received doses of insulin based on apparent misreadings of the patients' blood sugar levels, according to the inspectors.Inspectors also turned up the case of an 80-year-old woman, demented and self-destructive as a result of Alzheimer's disease, who became entangled in the straps of a protective vest that was designed to keep her from scratching her face or wiggling out of her chair and harming herself.

Records showed that on Dec. 20, she got twisted so tightly that it took two people to free her — one to hold the strap away from the skin and another to cut it. She was sent to the hospital with a swollen, strap-burned leg — and died the next day from a clot in her lung. Doctors attributed the clot to the obstruction of blood flow in her leg.

Yesterday, Mr. Sabatini said the findings were extremely serious but he believed Mrs. Raffel was taking the necessary steps to improve conditions there.

6325 Security Boulevard
Baltimore, MD 21207

JAN 0 9 1991

Janet A. Myder, Director
Regulatory Systems
American Health Care Association
1201 L Street, N.W.
Washington, D.C. 20005

Dear Ms. Myder:

I am responding to your request for clarification of the regulations, definition, implementation dates and survey procedures for nursing facilities participating in the Medicare and Medicaid programs.

I will provide a specific response to each of your questions as follows:

Q. What is the definition of "laboratory services" which is currently in effect and which is applied to nursing facilities' requirements under Medicare and Medicaid? Where is this definition located in the regulations?

A. The revised Federal requirements for laboratories and laboratory services located at 42 CFR Part 493 were published as a final rule on March 14, 1990, and became effective September 10, (except for participation in proficiency testing which is effective January 1, 1991) 42 CFR 493.2 defines a laboratory as "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. These examinations also include screening procedures to determine the presence or absence of various substances or organisms in the body."

The revised Medicare regulations for nursing homes located at 42 CFR Part 483 were published on February 2, 1989, and became effective on October 1, 1990. 42 CFR 483.75 specifies that long term care facilities providing laboratory services must meet the requirements of 42 CFR Part 493. The regulations continue to require nursing homes to meet essentially the same personnel requirements that have been in effect since 1974 and the newly revised uniform proficiency testing, quality control, quality assurance and recordkeeping requirements applicable to all facilities performing laboratory testing.

Q. Is glucose testing using an instrument considered a "laboratory service?" If so, why? Has the Health Care Financing Administration (HCFA) rendered the requirements of the facility performing this test comparable to the simplicity of the test?

R. A glucose test performed using any methodology, including measurement by an instrument, is and always has been considered a laboratory test. Glucose testing meets the previous and newly revised regulatory definition of a laboratory test or services since the procedure is a "... chemical ... examination of materials derived from the human body for the purpose of providing information used for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the Department to establish regulations based on test complexity and allows the Department to exempt from Federal regulations laboratories that perform only those tests that are simple and accurate to perform and pose no reasonable risk of harm to patients if performed incorrectly. On May 21, we published proposed regulations to implement CLIA that are based on test complexity. Comments received on this proposed rule are now being evaluated.

Q. Specifically which regulations (nursing facility, laboratory, and/or others) govern the provision of laboratory services in nursing facilities as of October 1, 1990? How has HCFA notified State and Federal surveyors of any changes in long term care requirements related to regulatory revisions?

R. Surveyors have been instructed to use the survey procedures and interpretative guidelines for nursing homes contained in the new nursing home guidelines (Transmittal 232), that references the State Operations Manual, Appendix C, Independent Laboratories, and Appendix A, Hospital Laboratories, to determine compliance of laboratory services provided by nursing homes. These instructions are being used until such time as our new survey procedures, interpretative guidelines and survey forms associated with the March 14 regulation discussed earlier are cleared for publication. The regulations implementing CLIA are in process, and it will be sometime before the regulations are finalized.

Q. When will (or were) survey procedures and guidelines be made available to State and Federal long term care surveyors to review a nursing facility's compliance with laboratory services at 483.75(l), effective as of October 1, 1990, in coordination with the new laboratory rules of 493? Where are these published and how have they been made available for providers and others to review?

R. The survey procedures, interpretive guidelines and survey forms to implement the March 14, 1990, final rule are contained in an issuance revision to Appendix C of the State Operations Manual. The instructions and forms are undergoing review for clearance and will be distributed to all State survey agencies and HCFA regional offices once approval is obtained. As with all State Operations Manual issuances, this publication will be available from the National Technical Information Service. We will supply the publication number and cost as soon as possible after publication.

Q. Is a prohibition against a nursing facility using a physician office to perform laboratory services on referral currently in effect? If so, what are the details of the prohibition? (e.g., can the physician perform laboratory services for his /her own patients in the nursing facility?) Until CLIA final rules for certificates are in effect, will HCFA make provisions to approve certain providers of laboratory services? The March 14, 1990 revisions to 483.75(l) state that, if a nursing facility refers specimens to a laboratory, the referral laboratory must be approved or licensed in accordance with the requirements of 493. How is this approval currently accomplished and known to the referring nursing facility? If no process is in effect, access in rural areas and others which are not close enough to a hospital for timely service will diminish as there are few alternative readily available sources of laboratory services.

R. Surveyors will conduct surveys using the regulations that were in effect prior to the March 14, 1990, revision of Federal requirements until such time as the new survey procedures, guidelines and survey report forms are cleared for use. Since currently we are in a transition period in the implementation of CLIA, which requires certification of *all* facilities conducting testing on human specimens, we will *not* take any enforcement actions on nursing homes that refer specimens to physician office laboratories. Accordingly, we intend to revise the final rule governing the Medicare and Medicaid Requirements for Long Term Care Facilities to permit nursing homes to refer specimens to physician office laboratories. When CLIA is fully implemented, all laboratories, including physician office laboratories and nursing homes providing laboratory services, will be subject to CLIA and must be certified under CLIA in order to participate in Medicare. Many physician office laboratories have voluntarily applied for Medicare approval as independent laboratories. If these facilities meet all applicable requirements, Medicare approval will be granted. Any questions concerning a facility's Medicare approval status should be referred to the appropriate State survey agency.

Q. HCFA, as the CLIA statute mandates, has proposed in a notice of proposed rulemaking implementing a portion of CLIA that certain simple tests will be placed on a waivered list and therefore not subject to the laboratory rules. Before this rule is finalized, why must a nursing facility performing these same tests be required to meet the similar and extensive laboratory requirements of 493?

R. Since 1974, nursing facilities have been subject to Federal regulations if they provide *any* laboratory services. As previously stated, nursing homes are subject to the same Federal requirements as hospitals and independent laboratories. The March 14 final rule merely *revises* current Federal requirements, it did not change present policy with respect to regulating nursing homes that perform laboratory services. CLIA provides the Department new authority to establish regulations based on the complexity of testing performed. CLIA requirements will *not* (and indeed cannot) apply until the effective date of the final CLIA regulations, so existing laboratory regulations remain in effect.

Q. Significant changes are taking place for which implementing guidelines and procedures have not been completed. The volume of changes in the new long term care requirements of participation and the new survey procedures implemented on October 1, 1990, as well as the revised laboratory rules effective on that date and on September 10, 1990, pose greatly increased workloads on long term care surveyors. Will Federal validation surveys expect that survey agencies will be fully able to survey the nursing facility laboratory services requirements?

R. In accordance with the Long Term Care Facility requirements of 42 CFR Part 483, laboratory services is a Level B requirement and as such is not routinely evaluated as part of a standard survey. Laboratory services would only be evaluated if an extended survey is conducted or a specific complaint is alleged concerning the quality of laboratory testing provided by a nursing home. We anticipate that State survey agencies will be able to conduct the limited number of surveys of laboratory services in long term care facilities necessary to evaluate compliance with Federal requirements.

I hope that I have clarified the Federal laboratory services requirements, survey procedures and interpretative guidelines that are applicable and will be applicable to nursing homes.

If you have further questions please contact Wayne Smith of my staff at (301) 966-6763.

Sincerely yours,

for Anthony J. Tirone
Director
Office of Survey and Certification
Health Standards and Quality Bureau

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date January 30, 1990

From Acting Director, Public Health Practice Program Office

Subject CDC Comments on ASPE Nonconcurrence

To Ms. Marcy L. Gross, Senior Policy Analyst, OASH/OHPE, HHS

We have reviewed the memo dated January 22, 1990 from Mr. Arnold R. Tompkins to Ms. Anna Boyd outlining the nonconcurrence of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) with HSQ-176-P.

Please find attached a summary of ASPE's position, the position taken by the Centers for Disease Control, and a discussion of each of the items of concern.

I hope that this document will serve as a useful framework for the discussion and ultimate resolution of the issues which have engendered the nonconcurrence position.

R.O. Valdiserri for
Joyce D. K. Essien, M.D., M.B.A.

cc:
J. Donlon
E. Hilyer
R. Irvin
T. Morford
D. Tolsma
R. Valdiserri

A. SUBJECT: PERSONNEL STANDARDS

ASPE POSITON:

The ASPE position is that the personnel standards as currently outlined in the draft NPRM (176) are "restrictive" and are "neither necessary nor sufficient to assure lab personnel's competency." Furthermore, the ASPE believes that these proposed standards would greatly increase the cost of laboratory services, especially in physician office laboratories.

Based upon Mr. Arnold Tompkins' memo of January 22, 1990, ASPE proposes the development of test and/or subspecialty specific competency-based personnel standards, and "to subject laboratories only to the personnel standards specific to the tests and/or subspecialties being performed." They propose the following:

- replace the proposed personnel standards with those already drafted by HCFA for hospitals (i.e. lab director is responsible for assuring that all other staff are trained and competent in the tests they perform and technical supervisors are required in several specialty areas).
- apply these standards to all laboratories except those that qualify for a certificate of waiver
- develop minimum requirements for the bench level in the statutory areas of 1) adequate prior training in the test performed 2) prior experience in the test performed 3) periodically demonstrated competence in the test performed and 4) adequate job performance
- make the director responsible for determining and documenting each employee's current competence and performance and for providing documented remedial action when necessary
- competency would be evaluated by a) periodic assessment by quarterly mailed proficiency testing performance b) successfully passing a written examination specific to the types of tests performed c) satisfactory completion of in-service training and d) on the job performance evaluation, conducted by a supervisor "with appropriate laboratory training and experience to evaluate the technical performance of the individual"
- require additional personnel requirements in education and experience for complex tests such as: cytology; toxicology; bacteriology; mycobacteriology; mycology; parasitology; and virology

- use the NPRM as a vehicle to solicit identification of other complex tests which might require specific additional personnel requirements
- strengthen the personnel standards by adding requirements in the following areas for all testing personnel: licensure; competency; in-service training; and individual performance

Other personnel issues raised by ASPE for public comment are:

- the regulations should stipulate that laboratory directors be present on site no less than 20 hours per week for labs with 12 or more bench personnel
- sanctions for directors and technical supervisors of labs which have had certificates revoked.

CDC POSITION:

- There should be two levels of personnel requirements consistent with the two levels of laboratories outlined in the complexity model (Appendix I).
- For a level I laboratory the director would be responsible for the training and experience of the staff performing testing—and there are no additional personnel requirements.
- In level II laboratories, where a more complex level of testing is being performed, the present personnel requirements for independent laboratories are proposed.

In considering the different levels of personnel requirements as they relate to the complexity of testing (see below), CDC, in conjunction with FDA, assumed that most physician office laboratories would either be categorized as exempt from regulation through the certificate of waiver, or would fall into the Level I category. Level I personnel requirements would also apply to most laboratories in the following settings: clinics for the treatment of sexually transmitted diseases; clinics for the provision of contraceptive care; laboratories associated with nursing homes; and laboratories associated with dialysis centers. Level II personnel requirements would, for the most part, apply to independent laboratories, hospital laboratories, and laboratories associated with group physician practices.

DISCUSSION:

Part of the difficulty in resolving the issue of personnel requirements in the clinical laboratory is that there is, at present, inadequate scientific information needed to guide policy development. Some studies have clearly shown that in certain subspecialties like microbiology, immunohematology, diagnostic immunology, parasitology, and hematology/coagulation, proficiency testing performance is positively and significantly correlated with personnel education and experience. However, other studies have shown contradictory findings. Many of these studies have been criticised on the basis of methodologic shortcomings and limits to their generalisability. Nevertheless, there does seem to be agreement with the concept that certain kinds of laboratory tests—because of the difficulty in performing them, the sophistication required to interpret them, or the dire consequences which could result if improperly conducted—require an increased level of personnel education and experience. Therefore the issue to resolve is not "whether" to apply differential personnel standards, but "when" to apply them, and in "what" manner.

The ASPE proposal would obviate the often discussed shortage of trained medical technologists, since they would be required only as general supervisors. However, it is not clear from ASPE's recommendations how all of the functions of a specialty program in medical technology could be subsumed by one or two college credits in a related area of biological science. For example, it would be helpful to see data indicating that individuals who have successfully completed a college course with a lab in clinical microbiology perform as well as those who have received a degree in medical technology which includes rotations within actual clinical laboratories.

Although the ASPE believes that their proposal is "simpler," that may not be the case, given the additional responsibilities placed upon the laboratory director for assuring the competency of the personnel working within the laboratory. How will competency be measured, by who's standards, and how often? A written examination alone may not be a sensitive enough measure of competency.

The CDC's position is one that recognises that certain areas of laboratory testing need not be performed by a medical technologist who has completed four years of specialty training. We are proposing that the only personnel qualifications for a level I laboratory be for the laboratory director, a trained and licensed M.D. or D.O.. Especially in the context of physician office laboratories, we recognise the practicality of being able to use trained personnel without requiring a baccalaureate degree. However, we believe that in a physician office lab setting, the primary care provider must be intimately involved in reviewing the results of testing, so as to minimise or negate the consequences of poorly performed testing.

B. SUBJECT: CERTIFICATE OF WAIVER

ASPE POSITION:

The ASPE position is that any "small possibility" of a false negative or false positive test posing an unreasonable risk of harm should be rejected. They believe that because of the "substantial amount of misdiagnosis in medicine generally" that it would be "less risky" to provide a test for which there is "a significant probability of error" than it would be to fail to provide the test altogether. They indicate that the risk to the patient of erroneous testing can be reduced by the context in which the test is performed, namely "the clinical question and the follow-up procedures." They believe that the limited number of waiver tests currently listed might influence physician office laboratories to fail to provide these tests so as to avoid Federal regulation.

ASPE recommends the following:

- remove Option I (Option I is the CDC/FDA recommendation that no waiver tests be identified until a process is established for establishing their conformity to the standards established by the Act.) from the NPRM
- expand the list of tests qualifying a laboratory for certificate of waiver to include most home use tests and most of the tests currently included on the Level I list
- do not collect detailed application data from waiver labs
- provide for a provisional certificate of waiver
- when evaluating a test for certificate of waiver, consider the clinical question to be addressed by the test, and the population to which the test will be applied

CDC POSITION:

In developing its proposed list of tests for certificate of waiver (Appendix II), CDC, in conjunction with FDA, considered the following:

- primary weight was given to the consideration that no risk of harm to the patient occurs if these tests are performed incorrectly
- the extent to which test reliability has been established such that the likelihood of erroneous results is negligible
- simplicity of the testing method
- availability of a home-use test methodology
- test presently exempt from regulation by various States and those proposed for exemption by various interested parties
- data from States with physician office laboratory regulations: number of physician office laboratories and level of on-site testing

Because of the paucity of scientific research in this area, CDC developed a proposal which was weighted toward protecting the interests of the persons being tested, i.e. minimising the potential for harm which might occur if persons were to receive an erroneous test result. Two options were proposed. In Option I, no list of tests qualifying laboratories for waiver would be provided until the establishment of a process by which an advisory committee would subsequently identify those tests which meet the criteria, as outlined in the Act. Option II provided a limited list of tests which would qualify a laboratory for a certificate of waiver (Appendix II). CDC also described a process whereby tests could be added or removed from this qualifying list based upon the new scientific information.

DISCUSSION:

Undoubtedly the issue of which tests should qualify a laboratory for a certificate of waiver exempting them from Federal regualtion could be resolved if there were adequate scientific research to shape policy, but such is not the case. In fact, the rationale for proposing Option I (i.e., no tests qualifying for certificate of waiver until they could be determined by an expert advisory committee) was in recognition of the fact that very limited data exist which specifically addresses the risk of harm to the patient should a test be performed incorrectly. This was also the reason for asking laboratories to submit information about the tests they performed—so that we could learn more about what level of testing is occuring in physician office laboratories across the nation. At present, there isn't precise information about how many physician office laboratories exist, or the extent of testing they perform on-site.

It is likely that the list of tests qualifying a laboratory for certificate of waiver will increase in the future, but it is important that this occur through an orderly process which promotes the use of data in decision making and incorporates input from representatives of the clinical and laboratory community.

It is true that the risk of failing to provide a test may be commensurate with or greater than the risk of providing a test which is inaccurate. However, the magnitude of the former does not obviate the importance of the latter, nor should it be suggested as a rationale for exempting a test from regulatory control. We know that harm can come to the patient through both routes. The Act clearly states that tests qualifying a laboratory for a certificate of waiver should be those which "have an insignificant risk of an erroneous results."

Physician office laboratories provide many tests, through referral, which they do not perform on-site. Therefore, it is not accurate to assume that a needed test will not be provided to a patient simply because a physician's office does not perform the test on-site.

Finally, it is true that the risk of an erroneous test can be minimised when it is considered in the context of additional information such as medical history, clinical findings, and additional testing. This supports the view that a primary care provider be intimately involved in interpreting the results of a test (as was recognised in the creation of a Level I laboratory).

C. SUBJECT: COMPLEXITY MODEL

ASPE POSITION:

The ASPE position is that because "very few tests" are classified as level I or waivered, physician office laboratories performing any level II test would be subject to the same laboratory personnel standards "as the largest independent laboratories performing many complex tests." They believe that this will exacerbate the competition for "limited bench expertise," i.e. trained medical technologists and technicians. They also "cannot understand why a Ph.D. would not be allowed to direct a level I laboratory."

ASPE proposes the following:

- the elimination of the proposed Level I and Level II distinction
- all laboratories which are not waivered be subject to "a uniform set of proficiency testing and competency-based personnel standards"
- allow individuals with master's degrees as lab directors if licensed by the state as lab directors

CDC POSITION:

In developing the complexity model, CDC, in conjunction with FDA, gave consideration to the following:

- primary weight was given to the consideration that no reasonable risk of harm to the patient occurs if these examinations and procedures were performed incorrectly
- requirements of subsections (f) and (g) of the Act
- diversity of laboratory facilities
- logistics of a regulatory program
- phasing-in of newly regulated laboratories with regulation which is appropriate to the level of testing complexity

Three levels of laboratories were identified:

- certificate of waiver laboratories (exempt from federal regulation)
- Level I laboratories which perform tests that, though relatively simple, are not exempt from potential harmful patient results if performed incorrectly (Appendix III)
- Level II laboratories which perform more complex testing

This structure was developed in recognition of the fact that test complexity does vary, both in terms of the methodologies employed and the expertise needed to interpret tests. For example, although performing a Gram stain may appear to be a relatively simple procedure, if it is not done correctly, infection may be undiagnosed and the individual could suffer serious consequences because of it.

That is why this procedure was placed in the level I category rather than the certificate of waiver list. Laboratories where testing is performed as an adjunct to some form of primary care, whether physician office laboratories, nursing homes, clinics for the treatment of sexually transmitted diseases, or clinics for the provision of contraceptive care, were envisioned to meet the criteria for Level I laboratories. This proposal incorporated the primary care provider as the "laboratory director" so that the additional information available to the primary care provider (e.g. clinical history, physical examination, and previous test results) would enable him/her to minimize the risk of erroneous tests results. That is also why we do not believe that a person with a Master's degree or a PhD should be qualified to become the director of a Level I facility.

DISCUSSION:

ASPE is concerned that many physician office laboratories would be forced to meet level II requirements, which would exacerbate competition for "limited bench expertise." This presumes that the list of tests qualifying a laboratory for level I status is static, which it is not. The proposal outlined by CDC would allow for an Advisory Committee which could provide technical assistance in evaluating additional tests which would qualify for level I status. Also, physician office laboratories do not currently perform on-site all of the tests which they order on their patients. It is presumed that physician office laboratories would simply refer those tests, not currently on the level I list, to reference laboratories rather than seek to fulfill the more stringent regulations of a level II laboratory.

D. SUBJECT: QUALITY ASSURANCE ISSUES

ASPE POSITION:

ASPE is concerned that the preamble of the proposed rule does not discuss in detail the issue of regulating labs for specific tests that pose "special problems," like urine testing for drugs of abuse or HIV. They suggest:

- that a confirmatory test for a positive urine drug screen be required when the test is performed as part of a screening program
- strengthen the regulation of HIV testing laboratories by increasing the number of PT challenges
- address the issue of HIV confirmatory testing

CDC POSITION:

The CDC agrees in principal with the inclusion of regulations which would address the items listed above. However, we believe that they should be addressed in such a way that the regulations will still be relevant as the technology changes.

APPENDIX I

PERSONNEL STANDARDS FOR THE
CDC-FDA PROPOSED COMPLEXITY - BASED MODEL

Type of Laboratory

Personnel	Certificate of Waiver	Level I	Level II
Director	NA	M.D., D.O.	M.D., D.O., Ph.D. Grandfather (Independent)
Supervisor	NA	Director	Technical and General Supervisior
Analyst	NA	Director certifies training and experience	Technologist or Technician

APPENDIX II

CDC-FDA PROPOSED LIST OF TESTS QUALIFYING FOR CERTIFICATE OF WAIVER

Dipstick or Tablet Reagent Urinalysis for the Following Analytes:

- Bilirubin
- Glucose
- Hemoglobin
- Keytone
- Leukocytes
- Nitrite
- pH
- Protein
- Specific gravity
- Urobilinogen

Fecal Occult Blood

Microhematocrit

Microscopic Examination of the Following:

- Urine Sediment
- Pinworm Preparation
- Vaginal Wet Mount Preparation

Ovulation Test - Visual color test for human luteinising hormone

Urine Pregnancy Tests

Whole Blood Clotting Time

APPENDIX III

CDC PROPOSED LIST OF TESTS QUALIFYING FOR LEVEL I CERTIFICATION

Qualifying Tests for Certificate of Waiver

ASO Screen - slide/card agglutination test

Cholesterol Screen - qualitative and semiquantitative determinations

CRP Screen - slide/card agglutination

Rheumatoid Factor Screen - slide/card agglutination

Glucose Screen - whole blood dip-stick method

Gram Stain (vaginal and urethral discharge)

Infectious Mononucleosis Screening - slide/card agglutination

KOH Preparation

Culture for colony counts for urinary tract infection - Not to include identification and susceptibility.

Erythrocyte Sedimentation Rate

Sickle Cell Screening - methods other than electrophoretic

102nd Congress, 1st Session .... H. Doc. 102-3

BUDGET OF THE UNITED STATES GOVERNMENT

OFFICE OF MANAGEMENT AND BUDGET

FISCAL YEAR 1992

IX.C. REFORMING REGULATION AND MANAGING RISK-REDUCTION SENSIBLY

Protecting and enhancing human health and welfare has always been an essential purpose of Government at all levels. The Federal Government both funds programs and imposes regulations to reduce risks to health and safety. Federal involvement in these areas has expanded enormously since World War II. There have been benefits, but also costs.

This section of the budget describes:

- The Administration's approach to regulatory reform.
- Problems associated with managing risk-reduction sensibly.
- Concepts for managing, and budgeting for, risk reduction.
- A 1991 Risk Management Budgeting Initiative to affect development of the 1993 budget and the regulatory agenda

THE ADMINISTRATION'S APPROACH TO REGULATORY REFORM

The Administration is committed to the prudent use of Federal regulation to achieve social benefits where these are not provided by the marketplace. This commitment is based on the principles of Executive Order Nos. 12291 and 12498 which require that Federal regulation be based on adequate information; that the benefits of Federal regulations exceed their costs; and that regulatory agencies develop an annual regulatory plan so that Congress and the public may know what regulations are likely in the coming year.

OMB's Office of Information and Regulatory Affairs (OIRA), working with the President's Council on Competitiveness, reviewed in 1990 over 2,100 rules—to ensure that necessary and cost-effective Federal regulations were promulgated and that the principles of Executive Order No. 12291 were applied. OMB also reviewed more than 3,000 agency information collection requests—to ensure they imposed minimal burdens, had practical utility, and were not duplicative. These reviews led to significant improvements.

The Administration has, in addition, reaffirmed the principle of Executive Order No. 12612, "Federalism," that decisionmaking be left to State and local governments wherever possible. Many policy decisions are best left to those levels of government closest to the constituencies the decisions will affect.

In conducting its reviews, OIRA emphasized benefit cost analysis and the use of performance standards that establish regulatory goals, letting the regulated community devise the most efficient method of meeting the standards. Performance standards govern outcomes and results rather than inputs and methods.

Where possible, the Administration has also encouraged the tailoring of regulatory programs and information collections to reduce their burdens on small business. Small business often lacks the capacity easily to absorb the costs related to regulatory programs.

PROBLEMS ASSOCIATED WITH RISK MANAGEMENT

There is risk in everything—in nature, in individual behavior, in the behavior of others. Table C–1 shows risks related to certain common events and activities.

- Out of every one million people in the United States exposed to the following risks, 196,000 die from all forms of cancer, 13,400 from motor vehicle accidents, 7,700 from home accidents, 960 from fires, and 17 from venomous bites and stings.
- Heart disease claims one of every four Americans, and much of this risk could be classified as both behavioral (smoking, diet) and natural (genetic predisposition, aging).
- Accidents involving motor vehicles claim one life in every 75; fatality risk is, of course, dramatically influenced by individ-

Table C–1. SELECTED RISKS TO LIFE

Cause of Death	Mortality Risk per million persons exposed	Average Risk per exposed individual
Smoking (1 pack/day)[1,2]	252,000	1 in 4.0
Heart Disease[6]	230,000	1 in 4.3
Cancer (all causes)[4]	196,000	1 in 5.1
Motor vehicle accidents[10]	13,400	1 in 75
Passenger cars	7,350	1 in 140
Passenger cars, restraints used	4,816	1 in 210
Passenger cars, restraints not used	8,757	1 in 110
Home accidents[4]	7,700	1 in 130
Homicide[8]	7,000	1 in 140
White females, 15–24 years[3]	400	1 in 2,500
White males, 15–24 years[3]	1,100	1 in 910
Black females, 15–24 years[3]	1,700	1 in 590
Black males, 15–24 years[3]	10,100	1 in 100
Drowning[8]	2,520	1 in 400
Cancer from exposure to medical X-rays[7]	1,400	1 in 710
Fires[8]	960	1 in 1,050
Cancer due to cosmic radiation from living at 5,280 feet instead of sea level[7]	560	1 in 1,800
Cancer from aflatoxin in 4 tablespoons of peanut butter per day[4]	560	1 in 1,800
Electrocution[8]	371	1 in 2,700
Cancer from radon in drinking water at 1.5 picocuries per liter[4]	259	1 in 3,900
Commercial aircraft accidents (one round trip per year)[4]	51	1 in 19,600
Cancer from chloroform in drinking water at EPA limit of 0.1 milligram per liter[4]	42	1 in 24,000
Lightning[8]	35	1 in 28,500
Bites and stings by venomous animals and insects[4]	17	1 in 58,800

[1] Based on a 70 year average lifetime

[2] Includes cancer and heart disease

[3] Based on 10 years within age category.

[4] Richard Wilson and Edmund Crouch, "Risk Assessment and Comparisons: An Introduction," Science, vol. 236 (April 17, 1987), pp. 267–270.

[5] Don Colburn, "The Risky Lives of Young Black Men," *Washington Post Health*, December 18/25, 1990, p. 7

[6] Richard Wilson and Edmund Crouch, *Risk-Benefit Analysis*, (Cambridge: Ballinger, 1982), Table 7–2

[7] *Ibid.*, Table 7–5.

[8] Estimated from Vital Statistics of the United States

[9] Derived from Department of Transportation, *National Transportation Statistics*, 1989

[10] Derived by DOT from Fatal Accident Reporting System (FARS)

ual behavior—miles driven, driver care, use of alcohol, use of seat belts and vehicle weight.

- The risk of death from homicide (about 1 in 140) is distributed unevenly across the population—for the 15–24 age group, for example, about 1 in 2,500 for white females, but almost 1 in 100 for black males (25 times greater).

Risks also vary by an individual's age and the duration of individual exposure. Whereas cancer and heart disease are highly correlated with old age, accidents are the leading cause of death up to the age of 44. Risky activities (e.g., automobile travel) may result in immediate death or serious injury, while other behavioral choices (e.g., smoking) involve long-term exposures that may lead to chronic illness or death later in life.

Cost Effectiveness of Federal Intervention

Table C–2 shows the risks and costs associated with selected Federal regulations.[1] As can be seen, the cost-effectiveness (in constant 1990 dollars) of regulatory actions varies over more than eight orders of magnitude—from about $100,000 per premature death prevented (for certain automotive safety features) to more than $5 trillion per premature death prevented (for regulating wood preserving chemicals as hazardous wastes). This range shows clearly that society's resources for reducing risk are being poorly allocated. On average, spending $2 million dollars on highway safety saves at least one life in just a few years. However, the same amount spent regulating cancer risks posed by wood preserving chemicals prevents one cancer case every 2.9 million years.

Table C–2 also shows that:

- Department of Transportation agencies (i.e., the Federal Aviation Administration and the National Highway Traffic Safety Administration) apply relatively consistent standards to determine whether benefits warrant costs. Most significant OSHA safety standards are similarly cost effective. But EPA regulations and OSHA health standards often entail very large costs for every premature death prevented.
- Programs intended to prevent deaths caused by injury are generally more cost-effective than programs aimed at reducing the mortality risk of environmental and occupational cancer. The cost of regulations aimed at reducing transportation injury risks have consistently remained under $2 million per death averted. However, many regulations targeted at occupational, environmental and dietary cancer risks have been extraordinarily costly.
- Many cancer risks from environmental exposures (excluding smoking and diet) are very small relative to other threats to human health. Nevertheless, about half of the significant regulations listed in Table C–2 (and a much larger percentage of the most expensive Federal regulatory actions) are aimed at reducing these same small cancer risks.

---

[1] All cost-effectiveness ratios provided are in constant 1990 dollars. These estimates can be compared to what can be discerned from individual behavior. A recent survey of this literature found estimates ranging from $1.6 million to $8.5 million. The authors placed more confidence in the estimates at the lower end of this range. *See* Ann Fisher, Lauraine G. Chestnut, and Daniel M. Violette, "The Value of Reducing Risks of Death: A Note on the New Evidence," *Journal of Policy Analysis and Management*, vol. 8, no. 1 (1989) pp. 88–100.

Table C–2. RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS

Regulation[1]	Year Issued	Health or Safety?	Agency	Baseline Mortality Risk per Million Exposed	Cost per Premature Death Averted ($Millions 1990)
Unvented Space Heater Ban	1980	S	CPSC	1,890	0.1
Aircraft Cabin Fire Protection Standard	1985	S	FAA	5	0.1
Auto Passive Restraint/Seat Belt Standards	1984	S	NHTSA	6,370	0.1
Steering Column Protection Standard[2]	1967	S	NHTSA	385	0.1
Underground Construction Standards[1]	1989	S	OSHA–S	38,700	0.1
Trihalomethane Drinking Water Standards	1979	H	EPA	420	0.2
Aircraft Seat Cushion Flammability Standard	1984	S	FAA	11	0.4
Alcohol and Drug Control Standards[1]	1985	H	FRA	81	0.4
Auto Fuel-System Integrity Standard	1975	S	NHTSA	343	0.4
Standards for Servicing Auto Wheel Rims[3]	1984	S	OSHA–S	630	0.4
Aircraft Floor Emergency Lighting Standard	1984	S	FAA	2	0.6
Concrete & Masonry Construction Standards[1]	1988	S	OSHA–S	630	0.6
Crane Suspended Personnel Platform Standard[3]	1988	S	OSHA–S	81,000	0.7
Passive Restraints for Trucks & Buses (Proposed)	1989	S	NHTSA	6,370	0.7
Side-Impact Standards for Autos (Dynamic)	1990	S	NHTSA	NA	0.8
Children's Sleepwear Flammability Ban[1]	1973	S	CPSC	29	0.8
Auto Side Door Support Standards	1970	S	NHTSA	2,520	0.8
Low-Altitude Windshear Equipment & Training Standards	1988	S	FAA	NA	1.3
Electrical Equipment Standards (Metal Mines)	1970	S	MSHA	NA	1.4
Trenching and Excavation Standards[1]	1989	S	OSHA–S	14,310	1.5
Traffic Alert and Collision Avoidance (TCAS) Systems	1988	S	FAA	NA	1.5
Hazard Communication Standard[3]	1983	S	OSHA–S	1,800	1.6
Side-Impact Stds for Trucks, Buses and MPVs (Proposed)	1989	S	NHTSA	NA	2.2
Grain Dust Explosion Prevention Standards[1]	1987	S	OSHA–S	9,450	2.8
Rear Lap/Shoulder Belts for Autos	1989	S	NHTSA	NA	3.2
Standards for Radionuclides in Uranium Mines[1]	1984	H	EPA	6,300	3.4
Benzene NESHAP (Original: Fugitive Emissions)	1984	H	EPA	1,470	3.4
Ethylene Dibromide Drinking Water Standard	1991	H	EPA	NA	5.7
Benzene NESHAP (Revised: Coke By-Products)[1]	1988	H	EPA	NA	6.1
Asbestos Occupational Exposure Limit[1]	1972	H	OSHA-H	3,015	8.3
Benzene Occupational Exposure Limit[3]	1987	H	OSHA-H	39,600	8.9
Electrical Equipment Standards (Coal Mines)	1970	S	MSHA	NA	9.2
Arsenic Emission Standards for Glass Plants	1986	H	EPA	2,660	13.5
Ethylene Oxide Occupational Exposure Limit[1]	1984	H	OSHA-H	1,980	20.5
Arsenic/Copper NESHAP	1986	H	EPA	63,000	23.0
Haz Waste Listing for Petroleum Refining Sludge	1990	H	EPA	210	27.6
Cover/Move Uranium Mill Tailings (Inactive Sites)	1983	H	EPA	30,100	31.7
Benzene NESHAP (Revised: Transfer Operations)	1990	H	EPA	NA	32.9
Cover/Move Uranium Mill Tailings (Active Sites)	1983	H	EPA	30,100	45.0
Acrylonitrile Occupational Exposure Limit[3]	1978	H	OSHA-H	42,300	51.5
Coke Ovens Occupational Exposure Limit[3]	1976	H	OSHA-H	7,200	63.5
Lockout/Tagout[1]	1989	S	OSHA–S	4	70.9
Asbestos Occupational Exposure Limit[3]	1986	H	OSHA-H	3,015	74.0
Arsenic Occupational Exposure Limit[3]	1978	H	OSHA-H	14,800	106.9
Asbestos Ban	1989	H	EPA	NA	110.7
Diethylstilbestrol (DES) Cattlefeed Ban	1979	H	FDA	22	124.8
Benzene NESHAP (Revised: Waste Operations)	1990	H	EPA	NA	168.2
1,2-Dichloropropane Drinking Water Standard	1991	H	EPA	NA	653.0
Haz Waste Land Disposal Ban (1st 3rd)	1988	H	EPA	2	4,190.4
Municipal Solid Waste Landfill Standards (Proposed)	1988	H	EPA	<1	19,107.0
Formaldehyde Occupational Exposure Limit[3]	1987	H	OSHA-H	31	86,201.8
Atrazine/Alachlor Drinking Water Standard	1991	H	EPA	NA	92,069.7
Haz Waste Listing for Wood Preserving Chemicals	1990	H	EPA	<1	5,700,000.0

70-year lifetime exposure assumed unless otherwise specified

[2] 50-year lifetime exposure

[3] 45-year lifetime exposure

[4] 12-year exposure period

NA=Not available

Agency Abbreviations.—CPSC Consumer Product Safety Commission; MSHA Mine Safety and Health Administration; EPA Environmental Protection Agency; NHTSA National Highway Traffic Safety Administration; FAA Federal Aviation Administration; FRA Federal Railroad Administration; FDA Food and Drug Administration; OSHA–H Occupational Safety and Health Administration, Health Standards; OSHA–S Occupational Safety and Health Administration, Safety Standards.

Source: John F. Morrall, III, "A Review of the Record," *Regulation*, Vol. 10, No. 2 (1986), p. 30. Updated by the Author, *et. al.*

The Context of Risk Management

Progress has been made in reducing health and safety risks. Life expectancy has increased from approximately 45 years at the turn of the century to the present 71 years for men and 78 years for women. Government helped with this, through immunization and public health programs. But longer lives have also resulted in more instances of chronic disease, such as cancer and heart disease, which now account for almost 60 percent of deaths.

Significant percentages of cancer and heart disease are attributable to such self-induced risks as smoking, alcohol abuse and poor diet. In fact, smoking is responsible for one in every six deaths in America—390,000 deaths per year (87 percent of lung cancer deaths, 30 percent of all cancer deaths and 21 percent of heart disease deaths). Alcohol abuse was responsible for half of the 47,000 highway deaths in 1988 and 40 percent of drownings. It is a major cause of cirrhosis, the ninth leading cause of death in the United States; it has also been linked to violence, homicide and suicide.

Indeed, Secretary of Health and Human Services Sullivan has pointed out that control of fewer than ten risk factors could prevent between 40 and 70 percent of all premature deaths, a third of all cases of acute disability and two-thirds of all cases of chronic disability. Most of these risk factors are within the control of the average citizen—stop smoking, wear seat belts, increase exercise, improve eating habits, end drug or alcohol abuse, seek early prenatal care and necessary medical examinations and immunizations.

The individual's perception of risk to health and safety depends on a variety of factors including the individual's confidence in private and public institutions. Those with confidence in America's institutions tend to rely on those institutions to implement general injunctions to reduce risks. Those who lack such confidence tend to want Government to regulate potential risks, assuming "worst case" scenarios for both risk and institutional behavior. The problem of perception is further complicated by what is often a lack of agreement among scientists and "experts."

Federal Budgetary Programs

The Federal Government now funds a variety of programs to reduce risks to health and safety. While many of these programs produce important benefits—Corps of Engineers flood control programs and Department of Transportation air safety programs—they are also costly. The budget requests $18.4 billion in 1992 for major health and safety risk-reduction programs, $91.4 billion over the 5-year period 1992–96 (see Table C–3).

Federal Regulatory Programs

Federal health and safety regulation has similarly resulted in significant benefits. Federal control of emissions to air and water and of the safe disposal of wastes can yield substantial environmental and health benefits. EPA's cost-effective rule phasing down the use of lead in gasoline has resulted in a marked decline in the ambient air levels of lead in U.S. cities. Similarly, Federal regulation of auto safety over the last 20 years has yielded important reductions in the annual toll of deaths and injuries on the Nation's highways.

The costs of regulation are, however, enormous—estimated as high as $185 billion annually in direct costs on the private sector and State and local governments—nearly $1700 for every taxpayer. Federal regulation is also intrusive. The Code of Federal Regulations contains well over 100,000 pages. In 1990, over 1200 new rules were added, and 1990 amendments to the Clean Air Act, alone, will require scores of new rules over the next several years.

REDUCING THE MOST RISK FOR THE BUCK

The standards for determining Government spending and regulatory program priorities are haphazard, leading to great disparities in benefits in relation to costs. To remedy this problem, the Administration is advancing a new initiative: Risk Management Budgeting—careful risk assessment and analysis of programmatic alternatives. Risk Management Budgeting should enable decision makers to reallocate scarce resources to produce both lower risks and lower costs.

Table C–3. EXAMPLES OF FEDERAL HEALTH AND SAFETY PROGRAMS [1]

(Budget authority; in millions of dollars)

	1992	1992–96
Department of Agriculture:		
Rural Water and Disposal Grants	225	1,125
Food Safety Inspection Service	425	2,124
Forest Service Firefighting	302	1,511
Environmental Protection Agency:		
Superfund	1,750	8,750
Sewage Grants	1,900	3,700
Air	505	3,523
Water	413	2,067
Hazardous Waste	334	1,672
Pesticides [2]	140	664
Department of Energy:		
Environmental Restoration		
Civilian	523	2,708
Defense	3,706	22,619
Uranium Enrichment Cleanup	124	799
Department of Commerce:		
National Weather Service	499	2,033
Corps of Engineers:		
Flood Control	1,000	5,200
Department of Labor:		
OSHA	302	1,511
Mine Safety	186	931
Department of Transportation:		
Highway Safety	437	1,886
Aviation Safety	598	2,448
Rail, Boating, Other Safety	771	3,156
Department of Defense:		
Environmental Restoration (Non-nuclear)	1,253	7,354
Department of Health and Human Services:		
Food and Drug Administration [2]	770	3,902
Medicare and Medicaid Survey and Certification	881	4,692
Centers for Disease Control	1,397	6,985
Total	18,440	91,359

[1] Selected programs $100 million or more annual budget authority

[2] Obligations (includes user fees).

Risk Management Budgeting

Risk.—Risk is the individual likelihood (e.g., one accident in over nine million airline flights) of harm (e.g., airplane crash) from some level of exposure (e.g., 110 million airline flights 1975–85) to a hazard (e.g., windshear at airports). Risk and exposure are combined to determine how much harm (e.g., 12 crashes and 400 lives lost) is caused. The term "risk" is also used to represent the sum of all individual risks, particularly when developing population estimates.

Risk-reduction Analysis.—Risk Management Budgeting requires the establishment of common units of measurement that enable risk reduction benefits and costs to be compared across a range of options and incremental funding levels within a program. This will allow the allocation of resources to achieve the greatest net benefits. Initially, Risk Management Budgeting will be applied to resource allocation within individual programs. In subsequent years, as many programs employ the technique, it will be possible to allocate resources across programs. Thus, benefit estimation requires the establishment of uniform government-wide standards for performing risk assessments.

Cost estimates should include the opportunity cost of the resources required by a given program (or program alternative) including both private and Federal budget costs. The opportunity cost of an alternative is the value of the benefits foregone due to the selection of that alternative.

Some programs address activities and events that may lead to immediate death (e.g., automobile safety), while others seek to reduce chronic or latent illness (e.g., reduced air pollution or the fostering of low-fat diets). The measure used in Table C–2 is cost per premature death avoided (adjusted for some of these differences, but not all).

Some suggest analysis should use "life-years" instead of "lives," since the public generally places a higher value on reducing risks faced by children than on increasing longevity *per se*. Others suggest it should also take into account ancillary benefits (for example, the commercial and private benefits of an improved highway system, in addition to reduced highway fatalities brought about by the system).

Good analysis must also avoid upper-bound estimates or "worst-case" scenarios; these mislead policy makers and the public and exaggerate the amount of risk reduction that can be achieved; they also create a systemic bias in favor of programs and policies that would eliminate exaggerated risk, while neglecting high risks elsewhere.

For example, the first five regulatory actions listed in Table C–2 have identical cost-effectiveness ratios of $100,000 per premature death avoided. However, the baseline mortality risk varies from five premature deaths per million persons exposed to almost 40,000—a factor of more than 7,000. Focusing exclusively on risk would have led decision makers to ignore the relatively low hazards from aircraft cabin fires, even though they were relatively inexpensive to remedy. Similarly, many of the regulations in Table C–2 have relatively large baseline risks that are very expensive to remedy—hence, their cost-effectiveness ratios are quite unfavorable.

If individual or population risk alone is used in setting program priorities, there is no guarantee that the programs selected are reducing risk sensibly. Large individual or population risks, that are very expensive to reduce, may not be cost-effective. Only by considering both the benefits and the costs of risk reduction can sensible decisions be made.

1991 RISK MANAGEMENT BUDGETING INITIATIVE

The 11 pilot programs selected for Risk Management Budgeting in 1991 span the interests of Government—from nuclear waste cleanups at the Department of Defense and the Department of Energy to regulation of clinical laboratories by the Department of Health and Human Services. Each program was evaluated for Risk Management Budgeting potential, as well as agency interest in applying Risk Management Budgeting to a particular program.

These pilot programs have been chosen because they:

- are aimed at mitigating health and safety risks;
- have substantial resource requirements over the next five years;
- are amenable to risk budgeting analysis in program priority settings; and
- are minimally quantifiable.

Budgetary Programs

There follow descriptions of four budgetary programs which will be subjected to Risk Management Budgeting in developing the 1993 budget. Agencies will, in consultation with OMB, complete the assessments during 1991.

Department of Energy (DOE).—Environmental Restoration and Waste Management is one of the fastest growing programs in DOE ($4.2 billion requested in the Budget for 1992). DOE has nearly 100 sites located in 31 States and territories containing various waste types (including radioactive, hazardous mixed, and sanitary wastes). Some of these date from World War II. DOE is developing a methodology for better setting cleanup priorities in order to maximize risk reduction across its many sites and, by 1993, will be ready to use this methodology more effectively in formulating future budget requests.

Department Defense (DOD).—The DOD Environmental Restoration Program is currently addressing the cleanup requirements of over 17,000 sites, with $1.3 billion requested in the budget in 1992. DOD is testing, a "Defense Priority Model" designed to use site-specific environmental data and other factors (including the proximity of hazardous wastes to human populations) to develop preliminary rankings of risk. The purpose is to assist decision makers in determining funding priorities for remedial actions among DOD sites requiring clean-up. The DOD model was developed in consultation with EPA and the States, and is being evaluated for technical validity by the National Academy of Sciences.

Defense/Energy.—While the safety record of the U.S. nuclear weapons stockpile has been impressive to date, the recent report of the "Drell Panel" raised health and safety concerns about current and future nuclear warheads and missile systems, primarily with respect to the risk of accidentally dispersing plutonium into the environment. DOD has budgeted funds to address some of these concerns, and, in conjunction with the Department of Energy, is studying whether additional steps should be taken. Existing analyses seem to focus primarily on the tradeoffs between the safety and military capabilities of weapons systems, rather than on the tradeoffs between safety and costs. Risk Management Budgeting would be used as a means of determining whether to augment the existing nuclear weapons safety program, and, if so, which risks to address first. It would provide a focused assessment of the actual gains in safety that can be made, and at what cost. Also, to the extent that more data on nuclear safety is required to provide an adequate benefit-cost analysis, Risk Management Budgeting would clarify which experiments are the most cost-effective to conduct.

Department of Health and Human Services (HHS) Immunizations.—Although over 95 percent of all children entering school have received their immunizations, low immunization levels among low-income urban infants and toddlers have been a factor in the rising number of measles cases (33 percent more in 1990 than in 1989). The budget includes an infant immunization initiative intended to evaluate the potential effectiveness of linking continued participation in low-income assistance programs (Women, Infants, and Children, Medicaid, Aid to Families with Dependent Children) with documented immunization of young children. Risk Management Budgeting can be an effective tool in reducing both health risks and future budget exposure.

Regulatory Programs

OMB will in 1991 undertake Risk Management Budgeting with respect to the following seven regulatory programs.

Food Safety.—The Department of Agriculture (USDA) is responsible for the safety of meat and poultry, and operates a universal inspection system intended to achieve such safety. The Food and Drug Administration (FDA) regulates foods not regulated by USDA based on a number of concerns, including pesticide residue tolerances set by the Environmental Protection Agency (EPA).

Two of these agencies are currently addressing certain of these risks though new regulatory initiatives—USDA regarding meat and poultry inspection, and EPA regarding pesticide regulation. Risk Management Budgeting will estimate food risks and the costs of the risk reduction so as to provide a useful benchmark for evaluating these initiatives and ensure that Federal expenditures obtain the highest possible return on investment.

Seafood Safety.—Industry, consumer groups, and several Congressional committees have all called for legislation to expand the existing mandatory seafood inspection program operated jointly by the Food and Drug Administration (FDA) and the Commerce Department's National Oceanic and Atmospheric Administration (NOAA). The National Academy of Sciences' (NAS) Institute of Medicine released in January 1991 the first comprehensive evaluation of the health effects of fishery products available to the consumer. The NAS concluded that (1) most health risks associated with seafood originate in the environment and should be dealt with by control of harvest or at the point of capture and (2) that, although inspection at the processing level is important to maintain safety of seafood, there is little evidence that increased inspection activities at this level would effectively reduce the incidence of foodborne disease.[1]

A joint Food and Drug Administration (FDA)/Center for Disease Control (CDC) risk assessment shows that the risk of acute foodborne disease from eating fish (excluding raw shellfish) is 1 in 2 million; from chicken, 1 in 25,000; and from raw shellfish alone, 1 in 1,400.[2] FDA's risk assessment thus supports the first conclusion of the NAS report: the health problem associated with seafood lies primarily with raw shellfish, and regulators should try to solve that problem in the water—before shellfish are harvested.

To address the shellfish risk, the budget increases spending for Federal seafood regulation by $23 million and proposes new Federal authorities that will help FDA, NOAA and State regulators prevent shellfish from contaminated waters from reaching the marketplace. Of the $23 million, $9 million will be recovered through user fees charged to seafood processors to cover the costs of incremental increases in inspections (in accordance with Administration policy to charge fees for Federal services that provide a private benefit to industry over and above any benefit to public health or safety). The budget also includes an additional $7.5 million in FDA (a 22 percent increase over 1991) and $6.5 million in NOAA (a 37 percent increase over 1991) to support FDA and NOAA research, consumer education efforts, and cooperation with States to improve seafood safety overall.

Seafood regulation should be based on science and epidemiology. It thus offers an important opportunity to test Risk Management Budgeting. Risk Management Budgeting should assist FDA, NOAA and the States in designing a regulatory and inspection system that maximizes risk reduction at minimum cost.

Occupational Exposure to Cadmium.—Cadmium is a heavy metal which appears in different forms in the workplace, some more toxic than others. Studies show a correlation between adverse health effects and high-level exposure, but these associations are much more uncertain at exposure levels commonly found in the workplace. Compounding the uncertainty of low-dose risk estimates is the fact that epidemiological studies show a synergistic (but unquantified) effect between cadmium exposure and smoking.

The Occupational Safety and Health Administration (OSHA) issued a proposed rule in February 1990 which would reduce the permissible exposure limit (PEL) to cadmium from the present 100 or 200 micrograms per cubic meter of air (μg/m^3), depending on its form, to 1 or 5 (μg/m^3). (Major industrial nations generally limit cadmium exposure to 50 (μg/m^3); none has set a limit below 20 (μg/m^3).) According to the latest *Regulatory Agenda*, OSHA plans to issue a final rule on cadmium exposure by September 1991.

OSHA has estimated that achieving the 1 (μg/m^3) PEL would prevent 14 excess cancer deaths and 13–189 kidney dysfunction cases a year at a cost of about $160 million per year, and compliance with the 5 (μg/m^3) PEL would prevent four excess cancer deaths and 11–41 excess kidney dysfunction cases per year at a cost of $57 million per year. Since estimates of both health effects may be exaggerated (particularly in light of observed synergism between smoking and cadmium inhalation), the Risk Management Budgeting effort will carefully review OSHA's risk assessment.

1988 Clinical Laboratory Improvement Amendments (CLIA 88) Implementing Rules.—The Health Care Financing Administration (HCFA) is responsible for surveying and certifying all Medicare participating clinical laboratories (hospital-based and independent) and interstate commerce laboratories, but not physician office laboratories. CLIA 88 was enacted to enhance the quality of laboratory services by extending Federal oversight to Medicare physician office laboratories (POLs) and establishing new quality assurance standards for cytology. CLIA 88 requires the Department of Health and Human Services (HHS) to promulgate rules outlining these standards for July 1991 implementation.

---

[1] Committee on Evaluation of the Safety of Fishery Products, *Seafood Safety*, National Academy of Sciences, National Academy Press, Washington, D.C., 1991.

[2] Center for Food Safety and Nutrition, Food and Drug Administration, manuscript in preparation, 1990. These risk calculations are based on a single, 4 oz. serving.

In May 1990, HHS published a proposed rule describing the standards. Most of the 60,000 comments received by the close of the comment period in September 1990 expressed concern regarding the effects of the rule on health care cost containment, access, and quality. While HCFA failed to provide a regulatory impact analysis, comments indicated that the rule would cost the private sector billions of dollars and have uncertain benefits. HCFA estimates user fees covering enforcement alone would cost $540 million. The Risk Management Budgeting effort will assist HHS and HCFA to access risks associated with physician office laboratories and design cost effective standards for them.

Corrective Action for Certain Hazardous Waste Treatment, Storage and Disposal Facilities.—Current regulations promulgated under the Resource Conservation and Recovery Act (RCRA) give the Environmental Protection Agency (EPA) authority to require "corrective action" only at Regulated Units (RUs) that have received hazardous waste since July 1982 Solid Waste Management Units (SWMUs) that have not received wastes since that date are not subject to these requirements. However, legislation enacted in 1984 directs EPA to develop a program to deal with these units as appropriate. In July 1990, EPA published a proposed rule that would require "corrective actions" at virtually any facility with a SWMU that has releases to the environment.

EPA has estimated that this rule would impose net present value social costs of $10–60 billion (other estimates are higher); $3–18 billion of these costs would be borne by the Federal government. (DOE estimates the cost of cleaning up its own facilities will exceed $100 billion.)

Human health and environmental benefits expected to be obtained through these actions have not been estimated, making it difficult for policy makers to determine a cost-effective regulatory strategy. EPA is now engaged in an effort to develop an improved analysis of both benefits and costs before policy makers select a course of action. Risk Management Budgeting will help to assure cost effective regulations of SWMU's and proper stewardship of scarce Federal budget authority.

Department of Labor (DOL).—Certain OSHA Regulations are more effective than others in reducing occupational illnesses and injuries. Risk Management Budgeting will enable OSHA to identify the most successful regulatory approaches. Currently, OSHA's regulatory planning is largely reactive. As a result, OSHA often regulates high-profile, low-risk hazards, while leaving low-profile, high-risk hazards unregulated. Risk Management Budgeting will help OSHA develop an analytical approach to ranking workplace hazards for the Administration's 1992 regulatory agenda—according to magnitude, preventability, and potential benefit of regulations.

Department of Transportation (DOT).—Motor vehicle accidents are responsible for about 45,000 fatalities and 3.2 million injuries annually. The Department of Transportation is now in the process of examining its highway safety programs to determine their relative cost effectiveness. Included will be projects that prevent crashes, such as evaluation of heavy truck antilock brake technology, as well as those that protect individuals if a crash were to occur. In addition, the Department is attempting to improve its risk analysis capability with the development of a National Advanced Driving Simulator. The Simulator, when completed, will be the most advanced of its kind in the world, and will significantly enhance the capabilities of the Department and safety experts to evaluate risk reduction strategies in highway safety. Risk Management Budgeting will assist DOT in designing its future regulation to target the highest risks and then regulate to reduce these risks in the most cost effective manner.

Mr. DINGELL. The Chair is going to recognize, first, the gentleman from Oregon, then the gentleman from New York, and then the gentleman from Georgia.

Mr. WYDEN. Thank you very much, Mr. Chairman, and I would begin by commending you, Mr. Chairman, because the fact of the matter is, for years now you have led the entire Congress in the effort to try to turn around this problem of inaccurate medical testing and it has been a pleasure to pursue this with you.

Mr. DINGELL. Would the gentleman yield?

Mr. WYDEN. I would be happy.

Mr. DINGELL. I want to thank the gentleman, but I want to make the observation that his efforts in bringing to light the problems here, focusing the attention of the Congress in this committee and others upon the situation, has been absolutely indispensable to the enactment of the legislation and will continue to be indispensable seeing to it that it is properly implemented and that it in fact works. And I want to commend the gentleman and thank him for his leadership in this matter.

Mr. WYDEN. Well, I thank the Chair for his graciousness, but I just want him to know how much I appreciate the many contributions he has made.

Mr. Chairman, over the years Congress has enacted a number of laws that Executive Branch agencies have been slow to implement. But the Clinical Laboratory Improvements Act of 1988 is different. The foot dragging in implementing this law is simply a matter of life and death. Because the Health Care Financing Administration is entering its third year of trying to subvert a law designed to improve the accuracy of medical tests. Americans are suffering needlessly.

If you were to develop a model gameplan to avoid complying with a congressional statute, it would look much like what the Health Care Financing Administration has done to the 1988 clinical labs legislation. HCFA ignored sensible obvious steps that would have expedited the law's implementation, such as calculating how many labs there were before the effort began to figure out the costs; holding public hearings to get direct interaction with experts in the field who could offer practical suggestions; and utilizing knowledgeable accrediting bodies in the private sector to the greatest extent possible to hold down the costs. All of these steps could have been taken by the Health Care Financing Administration and would have expedited the implementation of this law.

Last night I went back through the public record that was developed on this issue. More than 3½ years ago the record was documented, attesting to the frightening levels of inaccuracies in some medical tests. The College of American Pathologists told me, for example, that among 2700 of the very best laboratories in our hospitals, 10 percent failed to achieve acceptable levels of accuracy for platelet counts. Tests done to detect leukemia and bone marrow abnormalities. Cholesterol tests to prevent heart disease varied so widely that contradictory indications on the same sample could still be considered accurate.

In the face of these serious documented medical problems, the Department of Health Care Financing Administration has fought at every turn the need for clear reform legislation and tough measures that would tackle these problems.

Mr. Chairman, you noted in your opening statement that once again OMB is meddling and putting administration muscle behind efforts to delay the law's implementation. Like you, Mr. Chairman, I'm concerned about costs and holding down the price tag of compliance. But what price tag is OMB now putting on a life?

Clearly, there are simple medical tests and Congress intended that these be exempt from regulation. But the agencies charged with implementing the law are trying to use the simple test exemption to gut much of this legislation. And let's face facts. To a family that looses a loved one due to an inaccurate medical test, it will be of little comfort to learn that the Government thought the test was "simple" and should be unregulated.

Mr. Chairman, today is an especially important one. I look forward to working with you and our colleagues and appreciate the opportunity to participate.

Mr. DINGELL. The Chair thanks the gentleman. The Chair recognizes the gentleman from New York, Mr. Lent.

Mr. LENT. Mr. Chairman, I have no opening statement at this time, but I would like to yield to the ranking minority member, the gentleman from Virginia, Mr. Bliley, who has such a statement, I understand.

Mr. DINGELL. That would be appropriate. The Chair has great respect for the ranking minority member, as everybody well knows.

Mr. BLILEY. Thank you, Mr. Chairman. In 1988 Congress passed the Clinical Laboratory Improvement Amendments of 1988 or CLIA. This legislation sought to regulate testing facilities outside of the laboratory and required certification procedures, the conducting of studies, as well as the establishment of standards for the accreditation of laboratories by the Secretary of the Department of Health and Human Services. That was in 1988. Nearly 3 years later Congress mandates have gone unfulfilled. We are here today to find out why. Perhaps Congress was over ambitious in its regulations. Maybe the departments that worked for us was unable to accomplish CLIA's goals in the required timeframe.

Regardless of these reasons the concerns expressed by Congress through the enactment of this legislation are currently unaddressed. We will hear from a number of panels today and our hope is that not only can we get a sense of where we are in implementing CLIA, that we can discuss ways in which the medical community can, in a voluntary manner, help to insure that the tests given to the public are safe and are being performed by qualified personnel.

There are times when the wheels of government simply cannot spin fast enough. Perhaps this is one of those times. Our object today is not to cast blame, although those responsible for delaying the implementation of the law will be held accountable. We are here today to address the serious problem of unregulated clinical laboratories and to resolve this problem in the fastest manner possible.

Thank you, Mr. Chairman.

Mr. DINGELL. The Chair thanks the gentleman. The gentleman from Georgia, Mr. Rowland.

Mr. Rowland. I thank you, Mr. Chairman. Over the past couple of days I have been checking the files that I had in my office regarding people who have written me concerning CLIA and I find that there 111 different people who have written me over the past several months concerning the proposals about CLIA. Those who provide the care at home and I hear from them that they are concerned about the increasing costs of care that may come about. The delays in diagnosis and treatment, the shortage of laboratory personnel, the increasing shortage that might come about because of not having adequately put in place the rules and regulations concerning CLIA.

I would hope that HCFA would sit down with some people who provide the care, who are involved in giving laboratory diagnoses to work out the rules and regulations so that we can provide quality assurance that we need to have in our laboratories in providing health care on the one hand, but yet, on the other hand be sure that we do not in any way damage our access to care.

So, Mr. Chairman, I want to commend you for being very responsive to these concerns and having this hearing today and focusing attention on that so we can move on and assure quality health care for the people in our country.

Mr. Dingell. The Chair thanks the gentleman and the Chair observes that this subcommittee again was very interested in the proper enactment of the legislation as well as the proper administration of it and I want to particularly commend my good friend from Virginia, Mr. Bliley, for his help and assistance in that undertaking.

The Chair announces that our first panel is Dr. Bette C. Allen-Jones, M.D., Internist and Emergency Room Physician, Westfield, New Jersey, and Dr. Jack DeBoy, Director of Public Health and Chief, Division of Certification Training and Field Services, Laboratories Administration, Maryland Department of Health and Mental Hygiene, Baltimore, Maryland.

Dr. Allen-Jones and Dr. DeBoy, we thank you for being with us. The Chair, as you know, has the responsibility of administering this committee under the rules that we have had since the days of Sam Rayburn. Those require that all witnesses testify under oath.

Do either of you have any objection to testifying under oath?

Ms. Allen-Jones. No.

Mr. DeBoy. No.

Mr. Dingell. The Chair would observe that copies of the rules of the subcommittee, the committee and the House are there at the committee table to assist you in knowing your rights and also to enable you to understand the limitations that exist on the powers of the committee.

The Chair also advises that since you are testifying under oath it is your right to be advised by counsel during your appearance here. And the Chair inquires, do either of you desire to be advised by counsel during your appearance?

Ms. Allen-Jones. No.

Mr. DeBoy. No.

Mr. Dingell. Very well, then if you will each please rise and raise your right hand the Chair will administer the oath.

[Witnesses sworn.]

Mr. DINGELL. You may each consider yourself under oath and the Chair will recognize you in such order as you desire.

Doctor, I have to warn you, we have without exception the worst public address system in the whole of Washington, D.C., so get close to that microphone, please.

TESTIMONY OF BETTE C. ALLEN-JONES, INTERNIST, WESTFIELD, NJ. AND JACK DEBOY, ASSISTANT DIRECTOR OF LABORATORIES ADMINISTRATION, MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Ms. ALLEN-JONES. Good morning, Mr. Chairman and members of the subcommittee. It's an honor to be here this morning. The subject of my discussion—the diagnosis of sickle cell disease—is a complex one. I would like to give you a brief overview of the subject and then I would be happy to address any detailed issues during the question and answer period. My personal experience with the inconsistency of laboratory tests began in February 1988, during my pregnancy with my daughter.

Since my husband and I are of African decent, my obstetrician recommended that we be tested for sickle cell trait. As you may know, sickle cell anemia is an inherited disorder of the red blood cell which can cause chronic, serious and life threatening illness. It is most common among people of African, Mediterranean and East Indian decent. While a person with sickle cell trait has no evidence of illness, if both parents carry sickle cell trait there is a 25 percent chance that their child will have sickle cell anemia.

My husband and I were both diagnosed with sickle cell trait based on a positive sickledex screening test. The results of the screening tests were confirmed by a second, more-involved test called hemoglobin electrophoresis. It is important to diagnose sickle cell anemia early as chances for survival improve with early treatment. Prior to the availability of the technology for early diagnosis, many children with sickle cell anemia died during infancy due to overwhelming infections.

Consequently, based on our diagnosis of sickle cell trait the obstetrician and geneticists recommended amniocentesis. In this invasive procedure a needle is passed through the abdomen of the mother to withdraw fluid containing cells from the baby. There are only a few centers which have the technology to do the sophisticated testing necessary to reveal the presence of sickle cell disease in the unborn child. Therefore, the amniotic fluid testing was done in a second laboratory.

We were pleased when the amniocentesis results showed that the baby had sickle cell trait just like her parents. Four months later, in August of 1988, our healthy daughter was born. Our joy was reinforced by the State-mandated newborn screening which confirmed that our child had sickle cell trait. More than a year later, our local pediatrician recommended a hemoglobin electrophoresis to confirm the prenatal diagnosis. Imagine our surprise when this test appeared to show that our daughter had sickle cell disease. We were frightened for our daughter and angry at the apparent mistake in prenatal diagnosis.

This new diagnosis of sickle cell anemia prompted our physicians to repeat the original screening tests. This time at a fourth laboratory. The second screening test confirmed that my husband indeed had sickle cell trait. However, I had an uncommon type of hemoglobin which combined with my husband's sickle cell trait could produce a type of sickle cell disease in our daughter. We were devastated. We didn't know if the fevers that she developed were due to simple colds or if they could be a precursor to the life threatening infection. We wondered if the pain in her hand was coming from a bruise or if it was the beginning of a painful crisis which is a hallmark of sickle cell disease.

Over the next 1½ years additional specialized testing was necessary to determine the exact nature of my unusual hemoglobin. Finally, in November 1990, the Centers for Disease Control in Atlanta, Georgia identified the uncommon hemoglobin and determined that it was benign, not associated with any illness. So, after more than 2 years of testing we found that our daughter had this unusual hemoglobin combined with the sickle hemoglobin from her father and had not associated illness. However, it is equally possible, under other circumstances that this abnormal hemoglobin which was missed on the initial screening test could have caused devastating disease in combination with the sickle hemoglobin.

Much of anguish and anxiety could have been prevented by more complete and accurate prenatal testing.

Mr. DINGELL. Without objection, at this point, the Chair will insert into the record an affidavit received from Ms. Metta Cogburn. It describes the misdiagnosis of a tumor in her husband involved with the finding of melanoma by two dermatologists who both biopsied the tumor and assessed the samples themselves in their office. Had that cancer been properly diagnosed originally, the 5-year life expectancy of Mr. Cogburn would have been 50 to 80 percent.

When the cancer was finally detected, his 5-year life expectancy had been reduced between 15 and 20 percent. Mr. Cogburn died within 1 year of the final discovery of his cancer.

[The affidavit follows:]

DECLARATION OF METTA COGBURN

I, Metta Cogburn declare: I am the widow of Martin A. Cogburn who died of melanoma in 1989. He was seen for a growth on his temple area of his head by Dr. Robert McNamara, a Berkeley, California dermatologist on May 12, 1987. Dr. McNamara diagnosed the growth clinically as basal cell carcinoma, a slower growing cancer and less serious than melanoma, and treated it accordingly. Dr. McNamara did a biopsy on the tumor and looked at the biopsy slide under a microscope himself, also diagnosing the slide of the tumor as basal cell carcinoma.

Upon the tumor's return, my husband was referred to another dermatologist, Dr. Robert Herwick of San Francisco, who on August 28, 1987 also misdiagnosed the tumor as basal cell carcinoma and excised the tumor. Dr. Herwick biopsied the tumor and looked at the biopsy slide under a microscope himself, concluding that the tumor was a basal cell carcinoma. Dr. Herwick biopsied the tumor a second time on December 4, 1987 and again misdiagnosed the tumor as basal cell carcinoma.

Dr. Richard Sagebiel, pathologist and melanoma expert from the University of California Medical Center, San Francisco, testified that Dr. McNamara's failure to diagnose the May 12, 1987 biopsy slide as melanoma, was below the acceptable standard of care to be expected. He also testified that Dr. Herwick's failure to diagnose the August 28, 1987 biopsy slide and December 4, 1987 slide as melanoma was below the acceptable standard of care to be expected. Dr. Sagebiel testified that had my husband been properly treated on May 12, 1987 by Dr. McNamara that his 5 year life expectancy would have been between 50 percent and 80 percent. In August when Dr. Herwick misdiagnosed the cancer, his 5 year life expectancy had dropped to between 20 percent and 25 percent if properly treated, according to Dr. Sagebiel. By the time the cancer was discovered to be melanoma at U.C. Medical Center, his 5 year life expectancy was reduced to between 15 percent and 20 percent. He died within 1 year of the discovery that the cancer was melanoma.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 30, 1991.

METTA COGBURN.

State of California, County of Contra Costa.

On April 30, 1991 before me, undersigned, a Notary Public in and for said State, personally appeared Metta Cogburn known to me, to be the person whose name is subscribed to the within instrument, and acknowledged to me that she executed the same.

Witness my hand and official seal.

JAMES E. REED,

Notary Public in and for said State. My Commission Exp. Mar. 17, 1992.

Mr. DINGLE. Dr. DeBoy, the Chair will recognize you now for such statement as you choose to give.

TESTIMONY OF JACK DeBOY

Mr. DEBOY. Mr. Chairman, members of the Subcommittee on Oversights and Investigations, I am Jack DeBoy, Chief of the Division of Laboratory Licensure, Certification and Training, and Assistant Director of the Laboratories Administration in the Maryland Department of Health and Mental Hygiene.

I am here this morning to present the views of both the Association of State and Territorial Public Health Laboratory Directors, and the Maryland Department of Health and Mental Hygiene, on the continuing need to regulate most medical laboratory testing in this country.

Around 1975, advancing technology began pushing medical laboratory testing beyond its historical confines in hospital and independent medical laboratories. Before then, laboratory tests were performed most by and under the direction of professional laboratorians. Physicians who were the main clients of these laboratories, served as informed consumers and complained loudly whenever laboratory services didn't meet their expectations.

But today, in 1991, at least one of every four laboratory tests is performed by point-of-care laboratories located in private and government ambulatory-care clinics, physician office laboratories, skilled nursing facilities, and other entities, including our local shopping malls. These point-of-care laboratories provide a broad range of medical laboratory testing directly to the consumer-patient; and perform these tests using nonprofessional laboratorians. Consumers, who know little about medicine in general, know even less about laboratory medicine. Today's consumers of laboratory medicine must increasingly look to government to help protect them by assuring that all laboratories meet minimum standards of laboratory practice. Our citizens want laboratory test results to be accurate and reliable regardless of who performs their tests or where those tests are performed.

Blood glucose and cholesterol testing using portable fingerstick instruments provide good examples of the types of problems that occur when testing moves outside an actual laboratory and is not adequately regulated.

Fingerstick, blood glucose monitoring devices were developed and intended only, and I emphasize "only", to be used by known diabetics to self-monitor their glucose levels. These instruments are not intended to diagnose diabetes mellitus or to be used by multiple patients. Yet these are common practices and can lead to misuse of these instruments. In addition, test results from blood glucose monitoring devices only correlate with laboratory-based, reference test results between glucose levels of 50 and 400 milligrams per deciliter. This means that all laboratory-based glucose testing cannot be replaced by use of these portable monitoring instruments. For example, a patient in a diabetic coma should not be tested using a monitoring device because such a patient's glucose level will be 600 to 1000 or milligrams per deciliter of glucose, far beyond the linear range of the device's technology. Those patients must have a laboratory-based glucose assay every 1 to 2 hours until they have been stabilized and their glucose levels are lowered.

In February of this year the Maryland Department of Health and Mental Hygiene took action against a nursing home for improper use of a blood glucose monitoring device. In cases involving the deaths of two elderly diabetic patients, nurses wrongly relied upon glucose levels obtained from a fingerstick blood glucose monitor without understanding the device's limitations. For example, in one patient, readings of 402 and 498 milligrams per deciliter of glucose were recorded in the patient's chart. These readings have no meaning because they lie beyond the true range of the instrument. The patient's actual laboratory-based blood glucose measurement was around 1,600 milligrams per deciliter.

Back in 1986 a consensus panel sponsored by the American Diabetes Association, the Centers for Disease Control, the Federal Food and Drug Administration, and the National Institute of Diabetes, Digestion and Kidney Disease recommended quality control measures that verify the proper function of blood glucose monitors, reagent strips, and their users.

Today the essential components of a quality assurance program for any medical testing or screening instrument, whether it chemically measures blood glucose, cholesterol or other blood component, still includes: 1) a training program for the people who will perform the test, 2) calibration checks and/or control samples to evaluate instrument and reagent performance, 3) proficiency testing and periodic comparison of results with a reference laboratory, and 4) periodic review of operator technique and correction of any operator deficiencies.

Over and over again I hear that this or that latest technological advance has simplified some laboratory instrument to where anyone hired right off the street can effectively operate that instrument by simply pushing a few buttons. This isn't true now; and, as long as humans are in any way involved, will never be true.

Chu and co-workers showed in the February-1989 issue of Laboratory Medicine that operator-to-operator variability, lack of quality control, and lack of stringent staff training and education all contribute to variability and poor performance in fingerstick blood glucose monitoring.

Just last month the American Association of Bioanalysts compiled and distributed preliminary results of first quarter 1991 proficiency testing results covering over 4,000 glucose test sites that used fingerstick blood glucose monitoring instruments. These proficiency test results show that approximately 7 percent of glucose test sites called a normal test sample abnormal; 3.3 percent called an abnormal test sample normal when it was indicative of diabetes. The range of test results was also very disturbing. Some test results were off by more than 40 percent from what would be considered an acceptable measurement. This is a serious problem because glucose test values off by more than 20 percent can lead to inappropriate adjustment of insulin therapy.

When a person performs a blood glucose or other test on him or herself that individual personally assumes the burden of risk and liability; but when one person performs a test on another, the burden of risk and liability shifts to the person performing the test. In the latter situation the laboratory or person performing the test should be subject to minimum, government-mandated standards of laboratory practice.

Government-mandated standards are absolutely necessary. As a group of laboratory directors and regulators the Association of State and Territorial Public Health Laboratory Directors can state from experience that most providers of poor quality laboratory services do not voluntarily meet minimum standards of laboratory practice. In Maryland, for example, this was found to be especially true for many physician-office-laboratories and non-laboratory-based cholesterol testing services.

In June 1988 the Maryland Department of Health and Mental Hygiene found that poorly trained personnel and inaccurate cholesterol measurements were misclassifying many of the State's citizens. In the fall of 1988 Maryland also found that many unregulated physician-office laboratories in the State performed the same tests and used the same laboratory instruments as did regulated laboratories; however, the unregulated laboratories almost always lacked the most basic components of any laboratory quality assurance program, and employed personnel that were poorly trained to perform their laboratory duties.

Maryland found that the only way to assure that physician-office-laboratories and out-of-laboratory cholesterol testing services met minimum technical standards was to pass laws, promulgate regulations, and enforce nationally accepted technical standards. Healthcare providers, such as hospitals, and other nonprofit service organizations have had no problems meeting the cholesterol testing standards. However, several entrepreneurial cholesterol testing services that appeared to be more interested in profits than in providing the public with accurate cholesterol measurements have since stopped providing their services in the State. I should add that the aims of any program intended to improve point-of-care laboratory standards can only be met through repeated on-site inspections of these facilities.

Over the past 2 years the press has quoted various sources claiming that the proposed Federal rules under the Clinical Laboratory Improvement Amendments of 1988 will cost tens of billions of dollars to implement, will greatly increase the cost of the Nation's healthcare, and will force tens of thousands of point-of-care laboratories to drop or greatly reduce their laboratory services.

As a public health professional, government regulator, and taxpayer, I share these same fears. Federal rules and State regulations, to be both effective and fair, must not only protect the public but also improve and conserve the regulated medical laboratory industry. Writing fair, yet effective, regulatory standards for medical laboratories is a delicate balance; but it can be accomplished. I know this because States such as Maryland and Pennsylvania have done it. When the Maryland Department of Health and Mental Hygiene first proposed a law to regulate cholesterol testing, the biggest fear among legislators in the Maryland General Assembly was that the Department would over-regulate the testing, push its cost way up, and make it less available to the public. Maryland passed its law and the legislators' fears have not come true. Maryland has been able to effectively regulate cholesterol testing performed outside laboratories for only $30,000 a year. Maryland also developed and implemented a fair and effective annual Pap smear proficiency testing program for about $50,000 a year.

Maryland's newest and largest regulatory program for laboratories is one that regulates physician-office and other point-of-care medical laboratories. This program is expected to increase the cost of the average test performed in these previously unregulated laboratories by only 80 cents. Six cents of that 80 cents is going toward regulatory fees. The remaining 72 cents is being spent by the point-of-care laboratories themselves to implement and maintain their laboratory's basic quality assurance programs. This regulatory program is proving a success not only because the regulatory standards are fair, but also because Maryland is initially emphasizing education and regulatory flexibility along with regulatory enforcement.

I can also state that neither Maryland nor Pennsylvania has seen a significant number of point-of-care laboratories choose to drop or even reduce their testing services when faced with State regulation. Over the past 9 months Maryland has brought approximately 800 point-of-care laboratories under its regulatory umbrella; and fewer than a dozen have dropped or reduced testing menus rather than be regulated. Fair Federal rules under CLIA '88 should aim for similar results.

I will end my formal remarks by saying that both the Association of State and Territorial Public Health Laboratory Directors and the Maryland Department of Health and Mental Hygiene believe there are very few medical laboratory tests so simple that they rarely result in errors or pose no reasonable risk of harm if performed incorrectly. This is especially true where testing involves deceptively simple analytical instruments that can lead an unsophisticated purchaser or operator to assume all is OK as long as a numerical or printed result is generated.

Mr. Chairman and members of the subcommittee, I thank you for this opportunity to testify on this important subject.

[The following article was submitted:]

CONSENSUS STATEMENT

Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) has become a major adjunct to the care of individuals with diabetes mellitus in the past decade. It is an important technical advance that provides both the diabetic patient and the health-care team with vital clinical information that was previously unattainable. It is now possible for the diabetic patient and health-care personnel to measure and record blood glucose levels frequently with newly developed devices that are convenient to use and readily available. Individuals with diabetes mellitus as well as health-care professionals involved with their care must be trained to understand the purpose of SMBG, use the technique accurately, and record and make appropriate use of the results.

In view of the widespread use of SMBG, an examination and evaluation of medical and technical issues, training procedures, and general impact of SMBG was indicated. To address these issues, the American Diabetes Association, the Centers for Disease Control, the Food and Drug Administration, and the National Institute of Diabetes and Digestive and Kidney Disease convened a Consensus Development Conference on Self-Monitoring of Blood Glucose on 17–19 November 1986.

The conference consisted of invited presentations, panel discussions, and contributions from a large audience of health-care professionals and representatives from industry. A consensus panel with expertise in the areas of internal medicine, pediatrics, laboratory medicine, endocrinology, and diabetes education with backgrounds in clinical practice and academic medicine considered a broad spectrum of issues concerned with SMBG. The panel reached a consensus on the answers to these questions:

1. What is the intended and actual use of SMBG?
2. Is the design of SMBG devices adequate for their intended use?
3. To what degree are SMBG devices accurate and precise?
4. What is the reliability of these devices?
5. Is quality control in SMBG adequate?
6. Are patients adequately instructed on how to use the device, and in what manner is the instruction given?
7. How are the data generated by SMBG used in patient-care management?
8. How does SMBG influence medical outcome and day-to-day glucose control?
9. How is bedside glucose monitoring used in the hospital setting, and is this use appropriate?

1. WHAT IS THE INTENDED AND ACTUAL USE OF SMBG?

The primary intended use of SMBG is to assist in the management and evaluation of patients with diabetes. It has been estimated that 1 000.000 diabetic patients now use this technology.

The panel recommends SMBG for insulin-treated patients. It is especially important in *1*) pregnancy complicated by diabetes; *2*) patients with unstable diabetes; *3*) patients with a propensity to severe ketosis or hypoglycemia; *4*) patients prone to hypoglycemia who may not experience the usual warning symptoms; *5*) patients on intensive treatment programs, especially those using

---

The conference (17–19 November 1986) was sponsored by the American Diabetes Association, the Centers for Disease Control, the Food and Drug Administration, and the National Institute of Diabetes and Digestive and Kidney Diseases (NIH).

Reprinted from *Diabetes Care* 10:95–99, 1987.

Copyright 1987 by the American Diabetes Association.

portable insulin-infusion devices and multiple daily insulin injections; and 6) patients with abnormal renal glucose thresholds.

Although controversial, SMBG may be useful for patients not treated with insulin. SMBG must not be used to diagnose diabetes mellitus, and the role of SMBG systems in screening remains uncertain. Some insulin-treated patients may choose not to use SMBG routinely. Nevertheless, they should be trained in SMBG for use during emergencies. Patients who use SMBG should be properly trained and have a clear understanding of how the results of SMBG are to be incorporated into their individual treatment plans.

Monitoring systems involving visually or instrument-read strips are readily available from various sources. The panel recommends no change in this practice.

2. IS THE DESIGN OF SMBG DEVICES ADEQUATE FOR THEIR INTENDED USE

Properly used, the available technologies for SMBG are sufficiently accurate for patient management. All systems depend on a glucose oxidase—colorimetric reaction that occurs when a drop of blood is placed on a reagent strip. The intensity of the color that develops is proportional to the amount of glucose present. Some strips are designed to be read by reflectance meters, some visually, and some by both methods. All meters are battery powered and use solid-state electronics. The effective concentration range depends on the system but generally covers the clinically relevant range. Size, shape, and calibration techniques vary by manufacturer, but in general the glucose monitors are lightweight, portable, and easily calibrated. However, all available systems are highly dependent on user skills.

The panel recommends that future glucose monitoring systems be simpler and less dependent on user skill. Because current systems cannot be used by individuals with poor vision, the panel also recommends development of a reliable system for the visually impaired.

Finally, the cost of blood glucose monitoring is a concern, particularly the cost of reagent strips. For example, if a patient is performing 4 tests/day, the cost would exceed $750/yr.

3. TO WHAT DEGREE ARE SMBG DEVICES ACCURATE AND PRECISE?

The inherent accuracy (ability to obtain true values) and precision (ability to obtain reproducible results) of the SMBG devices are generally acceptable when evaluated under carefully controlled situations. In contrast, in actual patient-care situations the performance of these systems is not always adequate for making clinical decisions.

The following are factors affecting accuracy and precision.

User variability. The major source of variability in results obtained with SMBG devices is attributable to the user. In contrast to the satisfactory accuracy and precision of the systems under controlled laboratory conditions (coefficients of variation of 2–5%), up to 50% of the values may vary >20% from the reference values in general use. Some of these user variables are 1) size and placement of the blood sample, 2) timing of the test, and 3) removal of blood from strip. Some systems are more dependent on user skills than others. In general, results obtained with instrument-read strips may be more accurate than those assessed visually. However, many patients develop satisfactory skills in reading strips. Patients whose vision is not adequate to distinguish the colors should not use strips requiring such assessment.

Hematocrit. With available systems, the values obtained for blood glucose may be markedly affected by anemia or polycythemia. Anemia falsely elevates and polycythemia falsely depresses SMBG values. The magnitude of this effect may vary 4–30% for every 10% change in hematocrit, depending on the system used.

Hypoglycemia and hyperglycemia. SMBG may be unreliable in the hypoglycemic or severe hyperglycemic ranges. Caution should be exercised in interpreting values in these ranges.

Instrument malfunction. Although potentially serious, instrument malfunction appears to be an infrequent problem.

Defective reagent strips. Use of reagent strips that are outdated or improperly stored may result in inaccurate results.

Because of these variables, the panel recommends the development and implementation of adequate quality-control programs. The panel further recommends the development of a system that requires the user to perform standard quality-control and calibration functions before accepting a sample. Also, systems should be developed to ensure accuracy in the hyperglycemic and hypoglycemic ranges that are not influenced by changes in hematocrit. The goal of all future SMBG systems should be to achieve a variability (system plus user) of <10% at glucose concentrations of 30–400 mg/dl 100% of the time. However, the panel is aware that the accuracy required for clinical management has not been rigorously defined. Further research should be undertaken in this area.

Although most of the marketed systems perform well, there are differences in performance. To make an informed choice, the panel suggests that users consult health-care professionals before selecting a system.

4. WHAT IS THE RELIABILITY OF THESE DEVICES?

Blood glucose meters appear to be reliable. Users obtain acceptable customer service from the major manufacturers. According to one manufacturer, 60% of all inquiries are related to the function of the meter. Two-thirds of these problems can be solved via telephone, and most are related to user problems. These levels of reliability and customer service are commendable and are recommended for the entire industry. A desirable goal is that future instruments should be constructed so that after a malfunction they cannot be used without recalibration and verification that the system is operating correctly.

5. IS QUALITY CONTROL IN SMBG ADEQUATE?

Quality control is required to evaluate the reliability of user-generated SMBG data. In general, quality-control practices are inadequate. Quality-control procedures should verify proper function of the meter, reagent strips, and user. The panel recommends that complete quality-control programs be implemented by all users and supported by manufacturers and health-care providers. The essential components of a quality-control program include *1)* calibration checks to ensure that meter performance is adequate, *2)* measurement of control solutions of known glucose concentration to evaluate the performance of reagent strips and meters, *3)* comparison of results with a laboratory reference method, and *4)* periodic review of user technique with correction of deficiencies by a qualified health-care professional.

The manufacturer's responsibilities include encouraging users to perform periodic quality-control procedures and providing control solutions of known glucose concentrations to verify monitor performance. With current systems, the frequency of calibration and the magnitude of permissible error may vary according to the goals of therapy, the purpose of SMBG, and the ability of the individual patient.

Quality-control solutions do not measure errors generated during collection and application of blood to the reagent strip. Therefore, the precision and accuracy of all facets of the SMBG technique should be evaluated at regular intervals by comparing the patient's SMBG results with a concurrently obtained measurement on the same blood sample by a reference method. The same blood sample should be used to avoid uncertainty introduced by differences among capillary, venous, whole blood, and plasma samples. In most instances this is readily accomplished at the time of follow-up visits with the health-care professional.

Quality control is essential for health-care professionals who use SMBG in either a hospital or outpatient setting. The panel endorses the position of the Joint Commission on Accreditation of Hospitals (JCAH) that SMBG by nonlaboratory personnel must meet the following minimum standards:

- Personnel performing the test must be qualified through training. Training must be documented.
- There should be written procedures and policies for test performance, quality control, standardization and calibration of instruments, and reagent acquisition and storage.
- Quality control must occur daily and be documented.
- A basic accession record to include patient name, test, and date should be maintained to correlate with documented quality control results.

With current systems, SMBG measurements should be within 15% of the results of the reference measurement. Individuals who do not consistently meet this criterion should undergo further training until this goal is met. Similar goals of quality control should be pursued if SMBG is to be used for patient management in another setting, such as camp, school, or nursing home.

The panel recommends that manufacturers develop simple, inexpensive and efficient methods for quality control.

6. ARE PATIENTS ADEQUATELY INSTRUCTED ON HOW TO USE THE DEVICE, AND IN WHAT MANNER IS THE INSTRUCTION GIVEN?

The usefulness of SMBG depends on the accuracy of the results obtained. The accuracy of results depends on the use of proper technique, and the proper technique depends on the adequacy of training. Few data are available about the adequacy of the training of individuals to perform the test correctly. Training is offered in various settings, e.g., the hospital, clinic, pharmacy, and home.

Training is usually provided by health-care professionals, primarily nurses but also dietitians, pharmacists, manufacturer representatives, and physicians. In addition, many patients train themselves with manufacturer-provided training materials.

There are no standards for adequate training. However, the training procedure usually includes an explanation and demonstration of the proper procedure, a return demonstration by the learner, and a check of the learner's ability to accurately perform the testing procedure.

Approximately 50–70% of individuals who receive some sort of formal training are capable of obtaining a result within 20% of the reference method; however, performance may deteriorate over time. The most common reason for errors in SMBG is failure to follow instructions regarding proper application, timing, and removal of the blood sample.

The place of instruction is not a critical issue, but the quality of the instruction is critical. To be qualified, the trainer should *1)* demonstrate adequate knowledge of the performance characteristics of the SMBG methods offered, *2)* demonstrate accurate and precise blood glucose-testing technique with the system being used for training, and *3)* participate in ongoing proficiency testing and monitoring programs.

The panel recommends that the following components be incorporated into training programs: *1)* an assessment should be made by the health-care professional of the patient's abilities to properly use SMBG, *2*) the person with diabetes should be trained by a qualified trainer, *3*) trainers should assist the trainee in making the appropriate choice from the available systems, *4*) the trainer should demonstrate proper procedures and techniques including visual interpretation whenever possible to verify meter results, *5*) the trainee should demonstrate proficiency, *6*) the trainee should practice until the procedure is correct, *7*) the trainee should be instructed in the principles and importance of quality control, *8*) the trainer should provide immediate assessment of the trainee's skills, *9*) the trainer should provide periodic reassessment of the trainee's skills, *10*) the trainee should be instructed with the system that will be used at home, and *11*) documentation of the training outcome should be provided to the responsible physician.

7. HOW ARE THE DATA GENERATED BY SMBG USED IN PATIENT-CARE MANAGEMENT?

Blood glucose measurement is only one component of diabetes management and must be incorporated into the overall care plan of the person with diabetes mellitus. The SMBG component of the treatment plan should include a definition of blood glucose goals individualized for each patient, a schedule for blood glucose testing, a plan for data collection and use, and instructions for procedures to be followed during illness and emergencies (e.g., urine ketone determinations).

A recent American Diabetes Association survey indicates that many patients are not taught how to use SMBG data, and many health professionals do not review the data. The panel recommends that the proper uses of SMBG are

- to develop a data base relating to the characteristics of the individual patient's blood glucose profile. This data base should be reviewed regularly by the health-care professional with the patient to evaluate and modify the overall treatment program.
- to allow the patient to make day-to-day decisions, based on immediately obtained data, regarding changes in various components of the treatment regimen (i.e., hypoglycemic medications, diet, and exercise), either alone (after an appropriate period of diabetes education) or in consultation with the health-care team. Patients can be taught to use algorithms for insulin, diet, and exercise to achieve the desired level of blood glucose control. The availability of these data to diabetic patients provides them with the opportunity of minimizing hyperglycemia and documenting and avoiding hypoglycemia.
- to recognize and respond to emergency situations, such as incipient diabetic ketoacidosis and hypoglycemia.
- as an educational or training tool to enhance understanding of diabetes by patients and their families.

The patient's report of blood glucose measurements must be viewed with caution in regard to accuracy. Accuracy may be compromised by errors in technique, equipment failure, or overt misrepresentation. The data obtained from self-monitoring of blood glucose should be evaluated in conjunction with other parameters of blood glucose control, such as glycosylated hemoglobin and periodic checks of blood glucose measurements with a reference laboratory method. Discrepancies between patient-generated blood glucose data and the results of the glycosylated hemoglobin test must be investigated.

The panel believes that further studies are needed to develop and evaluate programs to organize, display, and analyze patient-derived data.

8. HOW DOES SMBG INFLUENCE MEDICAL OUTCOME AND DAY-TO-DAY GLUCOSE CONTROL?

It has not yet been shown that attempts to achieve normoglycemia prevent or reverse chronic complications of diabetes. However, the prevailing opinion among health-care providers specailzing in diabetes is that near normoglycemia may be a proper management goal. In pregnancy it is an essential goal. Without SMBG the goal of near normoglycemia is neither safe nor feasible in patients treated with insulin. Even with SMBG, extreme caution is necessary if this goal is to be pursued. Other treatment objectives that require SMBG include

- attempting to attain specific preset goals for blood glucose. To be effective, blood glucose goals must be reasonable and individualized.
- providing for increased flexibility in the patient's lifestyle. SMBG can assist patients in minimizing the dangers of varying mealtimes, engaging in strenuous physical activity, and ascertaining the impact of changes in insulin dosage and/or the dietary program.
- recognition and prevention of severe hypoglycemia.

SMBG is necessary (although not sufficient alone) to attain these treatment objectives.

SMBG may have other advantages. Many patients who use SMBG report considerable satisfaction from more active participation in their own treatment programs. Many also express a gratifying sense of enhanced control over their tretment, a feeling that has been conspicuously absent in previous treatment programs.

Regrettably, there is a paucity of evidence that SMBG has favorably impacted treatment outcomes, except in pregnancy. Carefully designed prospective studies are needed to investigate the impact of SMBG not only on blood glucose control but also on the quality of patient's lives and their sense of overall well-being.

9. HOW IS THIS BEDSIDE GLUCOSE MONITORING USED IN THE HOSPITAL SETTING, AND IS THIS USE APPROPRIATE?

During the last decade, the use of bedside blood glucose monitoring in hospitals has increased substantially. However, there has been serious concern regarding the accuracy and safety of bedside monitoring performed by nonlaboratory hospital personnel. The consensus of the panel is that the advantages of bedside monitoring can outweigh its potential hazards, as long as adequate measures are taken to ensure appropriate training and monitoring of all hospital personnel performing such testing. Appropriate applications of bedside monitoring include *1*) use as an education or training tool to enhance understanding of diabetes by patients and their families, *2*) use in emergency rooms for the rapid evaluation of patients with suspected hypoglycemia or hyperglycemia, *3*) assistance in determining appropriate insulin doses or infusion rates, *4*) assessment of the overall effectiveness of existing or new diabetes treatment regimens, *5*) help in the diagnosis or prevention of symptomatic or asymptomatic hypoglycemia, *6*) use in the perioperative management of surgical and obstetric diabetic patients, and *7*) use in the management of patients given total parenteral nutrition or glucose infusions.

Hospital personnel performing bedside glucose monitoring must be trained in the use of this technique and must participate in rigorous quality-control programs. These programs should include criteria for establishing *1*) the qualification of users, *2*) standardized procedures for the calibration and maintenance of equipment, and *3*) periodic verification of the competency of individual operators by comparing their results with those obtained by the hospital laboratory. These programs should be developed and implemented jointly by clinicians, nurses, and clinical laboratory personnel. In nursing services where bedside glucose monitoring is infrequent, it may be necessary for all glucose tests to be performed by laboratory personnel.

In any instance where the result of a bedside glucose measurement may make a critical difference in the management of a patient with a life-threatening illness, the result must be confirmed by a hospital laboratory glucose determination. Also, caution should be exercised in the interpretation of bedside monitoring results in patients with severe anemia or polycythemia.

CONCLUSIONS

Self-monitoring of blood glucose has proved to be an exciting addition to our armamentarium to ensure effective management of patients with diabetes. Notwithstanding the problems identified with implementation of this technique, we now have the capacity to rapidly obtain vital clinical information. Major problems needing resolution are to ensure quality control and to be certain that the data from SMBG are accurate and precise. We anticipate that with advances in technology, the implementation of quality-control programs, and the enhanced capacity for data analysis, remarkable progress will be made toward improving the care of diabetic patients in the future.

We make the following recommendations:

1. SMBG is recommended for insulin-treated diabetic patients.
2. No change should be made in the ready availability of SMBG systems from multiple sources.
3. Blood glucose monitors that are easier to use and less dependent on user skill should be developed.
4. A reliable glucose monitoring system for the visually impaired should be developed.
5. Complete quality-control programs should be implemented by all users and supported by manufacturers and health-care providers.
6. A glucose monitoring system should be developed that requires the user to complete quality control and calibration functions before accepting a sample.
7. Systems should be developed to ensure accuracy of SMBG in the hyperglycemic and hypoglycemic ranges and should not be influenced by changes in hematocrit.
8. The components of training as listed in the response to question 6 should be incorporated into training programs.
9. The proper uses of SMBG are *1*) to develop a longitudinal data base related to the patient's blood glucose profile; *2*) as an aid in making day-to-day decisions, based on immediately obtained data, regarding various components of the treatment regimen; *3*) as an aid in the recognition and response to emergency situations; and *4*) as an educational and training tool to enhance understanding of diabetes by patients and their families.

CONSENSUS DEVELOPMENT PANEL

John A. Colwell, MD, PhD, Chairman
Professor of Medicine, Medical University of South Carolina; Associate Chief of Staff, Research and Development, Charleston VA Medical Center, Charleston, South Carolina.
Jacqueline D. Dudley, RN
Coordinator, Diabetes Education Programs, Kilo Diabetes and Vascular Research Foundation, St. Louis, Missouri.
Jay M. McDonald, MD
Professor of Pathology and Medicine, Head of Division of Laboratory Medicine, Washington University School of Medicine, St. Louis, Missouri.

Robert Mertz, MD, PhD
  Section of Endocrinology and Diabetes, The Mason Clinic, Seattle, Washington.
Philip Raskin, MD
  Professor of Medicine, University of Texas Health Science Center at Dallas, Dallas, Texas.
Robert A. Rizza, MD
  Consultant in Endocrinology, Mayo Clinic, Rochester, Minnesota.
Julio V. Santiago, MD
  Co-Director, Division of Pediatric Endocrinology and Metabolism Center; Professor of Pediatrics, Washington University School of Medicine, St. Louis, Missouri.
Karl E. Sussman, MD
  Associate Chief of Staff for Research and Development, VA Medical Center; Professor of Medicine, University of Colorado Medical School, Denver, Colorado.
Donald S. Young, MD, PhD
  Professor of Pathology and Laboratory Medicine, Division of Laboratory Medicine, University of Pennsylvania, Philadelphia, Pennsylvania.

PLANNING COMMITTEE

Marlene E. Haffner, MD
  Director, Office of Health Affairs, Center for Devices and Radiological Health, Food and Drug Administration, Silver Spring, Maryland.
Stephen P. Heyse, MD, MPH
  Scientific Officer of the Diabetes Control and Complications Trial, National Institutes of Health, NIDDK/DEMD, Bethesda, Maryland.
Richard A. Kahn, PhD
  Assistant Executive Vice President, Scientific and Medical Affairs, American Diabetes Association, Inc., Alexandria, Virginia.
Alice Ring, MD
  Director, Division of Diabetes Control, Centers for Disease Control, Atlanta, Georgia.
Steven Teutsch, MD
  Chief, Technology and Operational Research Branch, Division of Diabetes Control, Centers for Disease Control, Atlanta, Georgia.

Mr. Dingell. The Chair recognizes now the gentleman from Oregon, Mr. Wyden.

Mr. Wyden. Thank you very much, Mr. Chairman.

It is very helpful to hear from two physicians with two very important perspectives.

Let me begin, if I might, with you Dr. DeBoy. Dr. Joseph of the Maryland State Health Department has indicated that there are reports of physicians requesting patients to perform tests in their own home and bring the results to the doctor, so that they can avoid regulation.

Is this an ethical or legal practice, and what is your State trying to do to address this?

Mr. DeBoy. Well, if the test is performed by the patient in their own home, then it's unregulated as far as the State of Maryland is concerned. I really feel that it's my—I should be able to answer on the ethical aspects of that.

If the physician—for example, it depends on the test protocol. If the physician can properly train a patient, for example, to use a cholesterol—I mean, a blood glucose monitor, that's fine. That's no problem.

But some of the problems that we have seen is where physicians—I have had at least one physician tell me that rather than be subjected to regulation in performance of blood glucose monitoring, he will simply hand the instrument to a patient in his office and let him conduct the test right there in his office, which is an attempt to skirt the regulations of the State.

Mr. Wyden. Is there an effort to determine if the physician is billing as well in your State? Are you trying to find that out?

Mr. DeBoy. OK. We have already approached and we are working with the State's Medicaid agency to determine which physicians in the State are already being reimbursed for laboratory services under Medicaid. At this point, we have not yet approached, for example Blue Cross and Blue Shield in the State of Maryland, but that would be a potential step in the future.

Mr. Wyden. With respect to your assessment of the job HCFA is doing, my sense is that you feel basically that the Federal Government has gotten in your way, that to the extent that you've been able as a State to put in place the kinds of controls that you feel your citizens need, that has been possible. But by and large, what the Federal Government has done is put hurdles in front of you as you try to address these concerns; is that correct?

Mr. DeBoy. I don't know if the correct term would be "hurdles." I agree, we have been able to put in place in Maryland programs which we feel are adequate and effective in doing what the Health Care Financing Administration would like to do.

Part of the problem comes from the fact that the way that the Health Care Financing Administration is trying to micromanage their programs, basically the States have no flexibility in the HCFA program, and one of my worries at this point—and I can see this coming already—is that the Health Care Financing Administration is going to put more and more of the burden upon the State agencies to implement their programs for them. And this is fine, but without come flexibility, without providing additional resources from that agency, the State agencies are not going to be able to implement HCFA either.

Mr. WYDEN. Is it correct that HCFA will not approve your PT for cytology?

Mr. DEBOY. That is correct. Our proficiency testing program was rejected by HCFA, because it did not meet all the fine, detailed specifications in HCFA's present requirements.

Mr. DINGELL. Would you say that again, please, sir?

Mr. DEBOY. The Health Care Financing Administration rejected Maryland's Pap Smear profiency testing program for acceptability because it did not meet all of the specific standards set by the Health Care Financing Administration.

Mr. DINGELL. If the gentleman would yield, then they have no standards of their own?

Mr. DEBOY. The Health Care Financing Administration has very specific standards. But to some extent, my feeling is that they are so specific that they're not going to find and they haven't found anyone to date to provide a program that is acceptable to HCFA.

Mr. WYDEN. So as I understand the consequences of this, I mean in human terms, we're talking about how your State wants to take steps to protect women against problems with Pap Smears—which are clearly designed to detect early cancer. Your State wants to do it. You've tried to move forward and tackle it. Not only will the Federal Government not help you, but they're getting in the way of your implementing your own rules; is that correct?

Mr. DEBOY. OK. It's not quite that way. Maryland has already implemented a program for Pap Smear proficiency testing. It's been up and running for 2 years, and as I said, it's functioning very well. But it is not acceptable to the Federal Government or cleared to meet Medicare certification under the Federal HCFA program.

Mr. WYDEN. So what are the human consequences here?

Mr. DEBOY. Well, in the State of Maryland, there are none, because the cytology laboratories in the State of Maryland still have to enroll and maintain enrollment in Maryland's proficiency testing program. So all of the cytology laboratories in Maryland and the citizens in Maryland are protected. But again, outside of Maryland, there are no programs other than in New York.

Mr. WYDEN. On this matter of——

Mr. DINGELL. Ask him if New York's test is approved.

Mr. WYDEN. Has New York's PT for cytology been approved?

Mr. DEBOY. To this date, it has not been approved either.

Mr. WYDEN. So in a sense, you can also bring us a national perspective as a State official, and your understanding is that only in the State of Maryland have you all been able to get proficiency testing in place for cytology?

Mr. DEBOY. In Maryland and New York. We both operate our proficiency testing programs in our own States.

Mr. WYDEN. And no other State has been able to get Federal approval for their program?

Mr. DEBOY. No other State has even attempted to do it at this point. I understand that California is trying to implement a program at the State level also.

Mr. WYDEN. OK. The only other question that I had for you, Dr. DeBoy, is this: has the publication of regulations under the old

CLIA law and the publication of new regulations under the CLIA '88 law caused confusion in the laboratory community? Are you getting a fair amount of questions from people simply saying, "What law is going to apply here?"

Mr. DeBoy. Now this is a tremendous problem, not just for the regulated laboratories, but it's also a tremendous problem for the State agencies that have to implement the HCFA regulations.

Since about the 1st of the year, my State inspectors, when they go out, have had to carry with them a 300-page manual listing hundreds of different items they're supposed to be looking for under the new CLIA regulations. It's a very difficult program to implement at this point.

Mr. Wyden. I think my time is up. Let me see if I can get in one additional question, Mr. Chairman.

Dr. Jones, one of the things that I think is so important about your testimony deals with public expectations.

During the hearings that we held, we found that people just assumed that the Government was regulating these laboratories tightly and that there really were efforts to weed out these problems of inaccuracies.

Were you, as a physician, surprised at the number of mistakes that were made by such a wide range of laboratories?

Ms. Allen-Jones. Yes, I was surprised personally as a parent, but also as a physician, and my primary physicians—the obstetrician, geneticist, and the pediatric hemotologis—were also surprised at the extent of the inconsistencies. Not only were inconsistent lab results received from the first commercial laboratory, but also from the State laboratory later, and it wasn't until more specialized testing was done by the CDC that we were able to get to the bottom of the problem, which in retrospect is something that could have been detected early on with the proper screening and to direct the tests after that.

Mr. Wyden. I thank you for that answer. I just find it very distressing that when a dedicated physician, like yourself, really is not in a position to know what kind of services and the quality of services they're getting at laboratories, you just cringe about the typical citizen going into this maze and trying to determine what quality services are and how they get them.

I think your testimony is very helpful. I appreciate it.

Thank you, Mr. Chairman.

Mr. Dingell. The time of the gentleman has expired.

The Chair advises that the gentleman proceeded for 8 minutes, so the Chair will recognize other members for 8 minutes.

The Chair recognizes my good friend from Virginia, Mr. Bliley.

Mr. Bliley. Thank you, Mr. Chairman.

Dr. Allen-Jones, following up on my colleague, Mr. Wyden's, question, how can similar problems in prenatal diagnosis be avoided in the future?

Ms. Allen-Jones. Well, for one thing, there's a need for internal quality control among the different labs. In the event that one lab has a disagreement, has a different outcome in a lab test, there is also a need for communication between the labs, and this is something that when we first found the discrepancy in the lab test, this was something that they were not able to do.

What happened immediately as a result of—my experience was that one of the referral labs that does more specialized testing now does not accept screening tests from outside labs. They repeat the screening tests themselves to confirm the abnormalities before they go on with the more expensive and time-consuming tests.

Ms. Bliley. And you think that is a better way to go?

Ms. Allen-Jones. Well, I think it's—I think it's a help. It's something that can be implemented right now.

As far as assuring quality control in the different laboratories, you know, I think that that's something that each individual lab has to do, and, you know, that's out of my realm.

Mr. Bliley. In your opinion as a physician and a patient, what is the role of the Sickledex and similar screening tests?

Ms. Allen-Jones. Well, we discussed this at length with the geneticist and the pediatric hematologist, and the problem with—this is a test which is used routinely with the expectation that you will find people who are carriers of the sickle cell trait and thus be able to advise them as far as having children.

The problem with the test is that, if it is done correctly, it picks up only the abnormal sickling hemoglobin. There are many other hemoglobins which can cause disease that this test cannot find, and as in this instance, if the test is done inaccurately, then it leads to a further cascade of testing, which these tests are necessarily inaccurate because of the first test.

So the Sickledex test is not really useful as a random screening test. It's something that needs to be regulated, and it is more accurate when it's used in conjunction with some other tests.

Mr. Bliley. Well, we understand that the Sickledex and similar tests are usually positive for both sickle cell trait and disease. Can you explain why this test was falsely positive in your case?

Ms. Allen-Jones. It's a mystery to me. The Sickledex test should have been negative, the first one should have been negative in my case. The special hemoglobin electrophoresis which is done with it should have picked up that my hemoglobin was not a sickle hemoglobin but another one.

There are various types of hemoglobin electrophoresis. Maybe the third or fourth laboratory that did our—that repeated our screening test went through the prescribed steps and found that this time my screening test was negative for sickle cell, and the hemoglobin electrophoresis showed that there was some other kind of abnormal hemoglobin.

Why it was not picked up in the first test in the commercial lab or at the State level, we don't know.

Mr. Bliley. What are the costs of these tests?

Ms. Allen-Jones. The Sickledex test is relatively inexpensive. The hemoglobin electrophoresis is more expensive. In addition, there are several different types, and you can imagine that the more sophisticated it is, the more expensive it will be.

However, the specialized testing done on the amniotic fluid was extremely expensive, and that test was done because of the inaccurate result of the basic inexpensive test, so that this inexpensive screening test generated a lot of expense. So it's maybe a false economy to rely heavily on that one alone.

Mr. **Bliley**. So you had four times the expense you should have normally had?

Ms. **Allen-Jones**. Yes.

Mr. **Bliley**. Thank you, Mr. Chairman.

Mr. **Dingell**. The Chair thanks the gentleman. The Chair recognizes now the gentleman from Georgia, Dr. Rowland.

Mr. **Rowland**. Thank you, Mr. Chairman.

Let me follow up just a little bit. Certainly you went through a very traumatic time, and I believe you said that similar testing was done in commercial labs, some in a State lab.

Ms. **Allen-Jones**. Yes.

Mr. **Rowland**. Do you know if there may be times when a laboratory test may be positive in one instance and another time negative because the test itself is not infallible and not the procedure that you go through? Could you expand on that a little bit?

Ms. **Allen-Jones**. It is true that you can do a test correctly and have a result that is inaccurate, and that may be what happened, and this is the sort of case where having the referral lab do a repeat test before they go one with their more expensive test, that's where this would be indicated, because it allows a second laboratory to check, and hopefully when they do the test, they don't have the inaccuracy.

Mr. **Rowland**. I'd always—when I do a test and I got an adverse result, I got a result I didn't want, I would always repeat the test myself at that time to sort of ensure myself as to the extent possible whether or not this was, in fact, a laboratory error or the validity of the test wasn't exactly what I thought it was before I would make a referral.

Is that what you're suggesting that should have been done?

Ms. **Allen-Jones**. Well, at the—when the initial prenatal testing was done

Well, when the initial prenatal testing was done, both the initial sickledex screening test and the subsequent electrophoresis appeared to confirm the diagnosis. One fit with the other, and seemed to be correct. There was no clue at that time that there was a mistake.

The only way that might have been picked up before undergoing the amniocentesis is if the second laboratory had repeated the first test. Really, there was no clue. We could not have told beforehand that it was inaccurate.

Mr. **Rowland**. Thank you.

Now, Dr. DeBoy, you are a Public Health official and an expert in the laboratory. Do you agree with what other experts have told us—namely, that there are no tests so inherently error proof and pose only an insignificant risk to the patient that they should be waived?

Mr. **DeBoy**. There are a few tests, a very small number, which could be waived. I think, if you're talking about something like the pinworm test, you know, it's a very basic type test. These really don't—even if they were misdiagnosed, they would not have a tremendous affect on the patient. These are very small in number, these types of tests.

As I testified to, I think anything that involves instrumentation basically requires more regulation. The reason I say this is that in many cases, the instruments themselves are fine. You know, they do what they were intended to do. But just running a specimen through an instrument does not provide and control for the parameters of that test. I mean, in the very beginning, it's not just properly pushing a button in the instrument. It starts very early on as to what test is needed, whether the correct test is selected by the physician, whether the patient is properly prepared before the specimen is withdrawn, whether the specimen is carried to the laboratory or transported in the proper environmental conditions, whether that specimen has to be treated in any way before it's actually tested by the instrument, whether the results come out in a timely fashion for the physician to use, and whether the results are interpreted and used properly by the physician. There are a whole lot of parameters involved in getting an accurate test result.

Mr. ROWLAND. A little knowledge is a dangerous thing.

Mr. DEBOY. Right.

Mr. ROWLAND. So would you say that additional training in the use of equipment, its limitations and how it should be used, and what to expect from it, could have prevented a lot of errors from happening?

Mr. DEBOY. Absolutely. Training of individuals is extremely important for any type of laboratory testing. I'm not advocating that everyone performing laboratory tests, particularly in the non-laboratory sites, be a professional laboratorian. I don't feel that that is necessary. But basic training as to what the parameters are of a test and what its limitations are, and how it should be provided are extremely important. Even if you take someone who does not have formal laboratory training, they should be provided with basic training; not just experience, hands-on experience, but also a little bit of book knowledge to be able to really understand the basics and how a test performs and what its intent is.

Mr. ROWLAND. There's a shortage of personnel in my area of the State of Georgia, laboratory personnel. The group that I practiced with, we had a laboratory in an office. I've talked with them recently, and they are not able to get a medical technologist. They are able to get a certified lab technician, and they are having to pay this person a technologist's salary because they just are not able to find one. Of course, they get checked by a clinical pathologist every month to be sure that things stay up to speed.

So I guess maybe you're saying, in situations like that, where it's not available, that people can be trained and checked on to do the work.

Mr. DEBOY. Right. I was faced with this problem in Maryland, and the way they have gone about solving it is, here again, we don't have enough medical technologists or pathologists or what have you to really work in all these laboratories, but every physician who is operating a laboratory in their own office, for example, will be required under Maryland regulations to obtain as a consultant, in many cases, a medical technologist, and that at least four times a year, they have to come into that office and help that physician set up and maintain the quality assurance for that laboratory.

Initially, these people are particularly important in helping the physicians first set up the quality assurance and quality control programs because most physicians do not have any experience in laboratory practice as such. They feel very inadequate in this area.

What we have found in Maryland is that when these medical technologists have been provided to the physicians, they make life much easier for the physician and take a lot of responsibility off their shoulder for initially setting up and meeting the State's laboratory standards.

Mr. Rowland. I see my time has expired. Thank you. Thank you, Mr. Chairman.

Mr. Dingell. The time of the gentleman has expired. The gentleman from Michigan.

Mr. Upton. Well, I thank you for your testimony, and I will pass on my questions. I look forward to hearing the testimony by the other panelists as well. Thank you, Mr. Chairman.

Mr. Dingell. The Chair thanks the gentleman.

The gentleman from Kansas.

Mr. Slattery. Thank you, Mr. Chairman. Most of my questions are for the folks from HCFA, but I just was wondering, in the experience that you all have had, are you satisfied with the classification on how HCFA has identified certain tests that must be considered Level 1 versus Level 2?

Maybe you covered this in previous testimony, but I wasn't here for the earlier comments today. But I'm just curious how they arrived at these decisions placing certain tests in Level 1 versus Level 2, especially as it affects the utilization of some certain machines that are capable of performing all the tests. I'm just curious, from your perspective, does this make sense what they have done, or not?

Mr. DeBoy. I'm not sure exactly how they came up with that classification system, either. I'm sure, to some extent, there were pressures put on them from a lot of different interest groups to try and make the thing fly, personally. There are a lot of problems with it. I don't know if I can go into the details—I'm not that familiar with them—but I know that the simpler you make a system, the better off it's going to be, the easier it's going to be to implement, and the more apt it is to work.

To have a tier, a three-tier system, which is the way it was originally proposed, is a very complex mechanism. In Maryland, you're either exempt from a State permit requirement or you have to permit, or you have to have a permit. There's only those two—either you're exempt or you're not. If you're not, then you have to meet all the standards. By trying to make a three-tier system, it's causing a tremendous problem even in trying to get consensus among the technical and scientific medical communities to implement these type of regulations.

Mr. Slattery. Dr. Jones, did you have any observations on that point?

Ms. Allen-Jones. No, I have no comments.

Mr. Slattery. Mr. Chairman, I have no further questions for this group, and I'll look forward to the testimony of the next panels.

Mr. Dingell. Dr. DeBoy, Dr. Allen-Jones, the committee is grateful for your assistance to us. We thank you for your presence this morning. Your testimony has been of great value. Thank you very much.

Ms. Allen-Jones. Thank you.

Mr. DeBoy. Thank you.

Mr. Dingell. The next panel is a panel composed of Dr. Gail Wilensky, Administrator, Health Care Financing Administration, Washington, D.C.; Dr. William L. Roper, Director, Centers for Disease Control, Atlanta, Georgia; and Mr. James B. MacRae, Jr., Acting Administrator and Deputy Administrator, Office of Administration and Regulatory Affairs, Office of Management and Budget.

Ladies and gentlemen, we thank you for your presence here today. If you would come forward and take seats, we will discuss the qualification of witnesses.

Ladies and gentlemen, you have heard the way the committee conducts its business. You will note that, for your assistance, copies of the rules of the committee, the subcommittee, the House of Representatives are there at the witness table to guide you in your appearance here today. They will inform you of both your rights as you appear and also the powers of the subcommittee and the limitations on the powers thereof.

The Chair advises that it is the practice of the committee, since it was created by Sam Rayburn some 40 years ago, to insist that all witnesses testify under oath.

Do you or any of you object to testifying under oath today?

Ms. Wilensky. No.

Mr. Roper. No.

Mr. MacRae. No.

Mr. Dingell. Very well.

Then, if you have no objection to testifying under oath, the Chair advises you that it is your right, since you are testifying under oath, to be advised by counsel during your appearance here.

Do any of you desire to be advised by counsel during your appearance here?

Ms. Wilensky. No.

Mr. Roper. No.

Mr. MacRae. No.

Mr. Dingell. Very well.

Then, if you have no objection to testifying under oath, if you would please each rise and raise your right hand.

[Witnesses sworn.]

Mr. Dingell. You may each consider yourself under oath.

Dr. Wilensky, we will recognize you to testify first. I suggest that you withhold, though, just for a second, until the members of the audience have received their copies of the statements here.

[Pause.]

Mr. Dingell. Doctor, I think there is enough order in the room that you may proceed.

TESTIMONY OF GAIL R. WILENSKY, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION; WILLIAM L. ROPER, DIRECTOR, CENTERS FOR DISEASE CONTROL; AND JAMES B. MacRAE, JR., ACTING ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Ms. Wilensky. Thank you.

Mr. Chairman and members of the subcommittee, I am pleased to be here to discuss the regulations to implement the Clinical Laboratory Improvement Amendments of 1988. CLIA introduced comprehensive reforms to the regulation of laboratory testing.

We have worked hard to develop regulations to implement CLIA. Scientifically, we have faced problems requiring new and innovative approaches to laboratory regulation. Administratively, we are challenged by the enormous scope of the new CLIA program.

As we develop these regulations to ensure the quality of laboratory testing, we are torn by conflicting incentives. From one perspective, we want to publish regulations as quickly as possible to implement the standards required by law.

On the other hand, we must take care to strike an appropriate balance within the statutory framework of quality, access, and cost. These are complex tradeoffs, and the rules are path-breaking. It has taken us time to arrive at a satisfactory conclusion.

We have faced these conflicting pressures internally, but we have also faced them externally, with many criticizing us for moving too slowly and at least as many criticizing us for moving far too quickly.

Implementation of CLIA is a task of tremendous proportions. The law requires that virtually all laboratories be regulated. We anticipate this will affect 300,000 to 600,000 laboratories, including those in physician's offices, shopping malls, and schools.

The law requires the development of an entirely new methodology for regulating laboratory tests. Hundreds of tests must be classified by their complexity and the risk associated with incorrect results.

Despite the enormity of the task, the Department has made steady progress with developing the regulations to implement CLIA. Four regulations to implement CLIA have been developed and published as proposed rules.

The proposed laboratory standards were published May 21, 1990, and specify the requirements laboratories must meet to be certified to conduct laboratory testing.

Development of this regulation was technically and scientifically challenging. The workload was divided between HCFA and the Public Health Service. HCFA had primary responsibility for the areas of personnel, quality control, quality assurance, recordkeeping, and computer systems.

Within the Public Health Service, the Centers for Disease Control was responsible for the complexity model, proficiency testing, and cytology. During an extended public-comment period, we received comments from nearly 60,000 individuals and organizations, an all-time high for the Health Care Financing Administration.

Dr. Roper will speak to the comments on the complexity model, cytology, and proficiency testing. I will address personnel standards and quality control.

Most commenters objected to the strict personnel standards proposed for laboratories that conduct Level II tests. The proposed rule anticipated that most Level II laboratories would resemble the traditional independent laboratory. However, we have learned that small laboratories are able to conduct a wide range of tests using sophisticated but simple-to-operate instruments.

Therefore, most small laboratories, including physician office laboratories, will be Level II laboratories and would have to have highly-specialized staff.

On the other hand, many comments from technical personnel expressed concern about excessive reliance on the so-called goof-proof machines operated by unskilled people. These commenters stressed that testing accuracy also depends on the knowledge and the skill that trained professionals bring to the laboratory.

On quality control, manufacturers recommended that we provide greater flexibility on the minimum quality control checks that laboratories perform on their instruments. Some manufacturers suggested that we rely entirely on their instructions for internal quality control. However, it is not clear whether manufacturer's instructions alone would provide adequate quality control.

The comments have provided us with depth of information that is guiding our development of the final rule. Once the revised complexity model is developed, the personnel standards and other sections of the regulation will be coordinated with it. We anticipate publication of the final rule for laboratory standards this winter.

The law requires that user fees finance the cost of implementation, administration, and enforcement of the new regulatory program.

The proposed user-fee rule was published August 3, 1990. It specifies the application process for laboratories and how fees will be set. Laboratories will be required to obtain provisional certificates until they can be inspected to determine their compliance with the CLIA regulations. After publication of the final regulation on laboratory standards, laboratories will apply for a certificate of waiver, a certificate of accreditation, or a regular certificate.

The type of certificate will depend on what type of test the laboratory performs and how it is surveyed for compliance with the Federal regulatory standards. A draft of the final user fee rule is under review, and we expect that it will be published in May or June of this year.

The proposed accreditation regulation was published on August 20th of 1990 and specifies the condition under which accrediting organizations or States can qualify to approve laboratories as meeting all four requirements. A draft of the final accreditation rule is being developed, and we anticipate its publication in October.

The proposed enforcement rule specifies intermediate sanctions to enforce compliance with CLIA requirements. Intermediate sanctions may include a directed plan of correction, State on-site monitoring, or civil money penalties. The proposed enforcement rule was published April 2nd of 1991, and the public comment period will close on June 3rd. We expect to publish the final rule this winter.

The four CLIA regulations have been a priority at both HCFA and the Public Health Service. We are optimistic that we will be able to resolve the many complex technical issues that were raised in the public-comment period.

The two regulations most important for implementation, the laboratory standards and user fees, are on track. User fees will be published in the summer, and laboratory standards will follow in the winter. All the regulations will be published by the early part of 1992.

Thank you. I would be happy to answer your questions.

[Testimony resumes on p. 78.]

[The prepared statement of Dr. Wilensky follows:]

STATEMENT OF
GAIL R. WILENSKY, PH.D.
ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here this morning with my colleague, Dr. William Roper, Director of the Centers for Disease Control, to discuss the regulations to implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Background

The Health Care Financing Administration (HCFA) regulates laboratories that participate in the Medicare and Medicaid programs. In 1979, responsibility for the CLIA program was transferred to HCFA from the Centers for Disease Control. Since then, HCFA has been the lead Federal agency responsible for ensuring the quality of clinical laboratory testing in this country, monitoring approximately 12,000 laboratories participating in Medicare or Medicaid, or engaging in interstate commerce.

Historically, these laboratories have been regulated on the basis of location; that is, whether they are in hospitals or are freestanding, independent laboratories. In the past, these laboratories represented the preponderance of laboratory testing. However, sophisticated, low cost technology has diffused into physicians' offices where increased testing is now occurring. Physician office laboratories were generally excluded from regulation.

The Clinical Laboratory Improvement Amendments of 1988 introduced comprehensive reforms to the regulation of laboratory testing. The law requires that all laboratories that test human specimens for health purposes in the United States and its territories be subject to regulation. Regulation will be based on the complexity of the test and the risk associated with erroneous test results, i.e. a "complexity model."

To support this enormous regulatory program, the law requires that laboratories pay fees for certificates and surveys. CLIA permits the use of private, nonprofit accrediting agencies and State licensure programs, approved by the Federal government, to certify that laboratories meet their standards in lieu of Federal standards. Enforcement actions, as specified in the law, will be used when laboratories fail to comply with the requirements for certification.

Implementation of CLIA is a task of tremendous proportions, involving several components of the Department of Health and Human Services. The law necessitates development of an entirely new methodology for regulating laboratory tests that requires classifying hundreds of laboratory tests by the skill needed to perform them, the methodology used, and the potential for adverse health outcomes if performed inaccurately.

Within the scientific community, there is no empirical standard to make these complexity classifications, nor is there general consensus as to how exactly this should be done. The expansion to all laboratory tests, including tests performed in physician offices, shopping malls, schools, and office laboratories, means we will regulate 300,000 to 600,000 laboratories. An entirely new infrastructure must be established to collect fees, inspect laboratories, and enforce compliance.

Despite the enormity of the task, the Department has made steady progress with developing the regulations necessary to implement CLIA. In March 1990, shortly after I arrived at HCFA, the portions of CLIA concerning proficiency testing and national standards for quality assurance in cytology were included in a final rule affecting Medicare, Medicaid, and interstate laboratories.

Four regulations to implement CLIA have been developed and all four have been published as proposed rules. The proposed rule specifying Federal laboratory standards based on the complexity model was published May 21, 1990. The proposed user fee rule was published August 3, 1990, followed by the proposed rule granting deeming authority for accreditation on August 20, 1990. Intermediate sanctions were proposed in a rule published April 2, 1991.

Publication of each proposed rule is typically followed by a 60 day public comment period. The comment period is an opportunity for the public to express its concerns with the rules and suggest changes for the final rule. All comments are read carefully and considered in preparation of the final rule. The final rules will include responses to the public comments with an explanation of our reaction to the comments.

Description and Current Status of the Proposed Rules

Laboratory Standards

This proposed rule specifies the standards all laboratories subject to CLIA must meet to be certified to conduct laboratory testing. It includes standards for the complexity model, personnel, quality assurance, quality control, proficiency testing, and cytology, among others. As required by statute, the standards are based on the complexity of the test and risk factors associated with erroneous test results.

In the proposed rule all laboratory tests were assigned to one of three categories: Waiver, Level I, or Level II. Waiver tests are simple to perform and present a low risk of harm to the patient if the test is performed incorrectly. Level I tests are more complicated to perform and there may be a reasonable risk to the patient if performed incorrectly. Level II tests must be performed by trained personnel and there may be substantial risk to the patient if performed incorrectly.

Development of the proposed rule was technically and scientifically challenging. The workload was divided between HCFA and the Public Health Service (PHS). HCFA had primary responsibility for the areas of personnel, quality control, quality assurance, recordkeeping, and computer systems. Within the PHS, the Centers for Disease Control (CDC) was responsible for the complexity model (with assistance from the Food and Drug Administration (FDA) on instrumentation), proficiency testing, and cytology.

In November 1988, HCFA held a major symposium attended by laboratory professionals, manufacturers, accrediting organizations, and physicians to solicit ideas on how best to regulate laboratories under CLIA. The American Medical Association, the Health Industry Manufacturers Association, the Commission on Office Laboratory Accreditation, the College of American Pathologists, and the Joint Commission on Accreditation of Healthcare Organizations all attended along with many others.

Throughout the next year, HCFA met informally with numerous professional organizations and individuals about their ideas for the complexity model. State regulatory models and their experiences with those models were also examined.

There was great difficulty in reaching a scientific consensus on this model. No one was sure how many levels there should be or which tests to put in which levels. There were concerns about which tests are of such low risk that they can be included in the waiver category. Concerns were raised about possible shortages of personnel and effects on access, including access for underserved populations and in rural areas. The proposed rule was the best attempt to address these concerns given the information available at the time.

Due to the extensive interest in the proposed rule, HCFA took the unusual step of providing a 90 day comment period and then extending it by 30 days. We received comments from nearly 60,000 individuals and organizations.

Using the same workload allocation, the comments were divided between HCFA and the PHS. The comments were coded and entered into a computer data base, enabling us to determine how many comments were received on specific subject areas or from different types of commenters. For example, we received over 15,000 letters on the complexity model, nearly 23,000 on personnel standards, almost 19,000 letters from physicians, and over 550 from organizations.

I will now describe the major issues raised and the process HCFA followed in reviewing the comments on personnel standards and quality control. Dr. Roper will describe the concerns raised about the complexity model, cytology, and proficiency testing and the process used by the CDC to analyze the comments.

The comments HCFA received often raised technical and scientific issues. For example, most commenters on personnel objected to the degree of regulation of personnel qualifications for laboratories that conduct Level II tests. The proposed rule anticipated that most Level II laboratories would resemble the traditional independent laboratory, and outlined extensive supervisor and technical personnel qualifications. However, we have learned that small laboratories are able to conduct a wide range of tests using sophisticated, but simple to operate instruments. Therefore, most small laboratories, including physician office laboratories, would be Level II laboratories under the proposed rule and have to hire highly specialized staff.

On the other hand, many comments from technical personnel expressed concern about excessive reliance on "goof-proof" machines that are operated by unskilled persons. These commenters stressed the irreplaceable knowledge and skill that trained professionals bring to the laboratory. They argue that the accuracy of a test result is dependent not only on the equipment used to perform the test, but also on the knowledge exercised in collecting and handling specimens and in interpreting that the result is correct. Our challenge is to weigh these comments and try to find accommodation for the small laboratories without compromising the quality of laboratory testing.

In the area of quality control, we heard from manufacturers recommending that we provide greater flexibility in mandating minimum quality control checks that laboratories must perform on their instruments. Some manufacturers suggested that we rely entirely on their instructions for internal quality control. However, it is not clear whether manufacturers have products of equal quality or recommend equivalent standards for internal quality control programs.

We brought several teams of laboratory specialists from our regional offices to our headquarters in Baltimore to review and summarize the comments. They have drafted responses to the comments. Although we have made significant progress in responding to comments, there is still much work to be done.

The PHS is working on identifying alternative approaches for the complexity model, the core of the regulation. Once the revised complexity model is developed, we will integrate the personnel standards and other sections of the regulation with it.

The final rule will then undergo internal review. This is a process of independent analysis within the Department to assure the accuracy, equity, and validity of the regulation. To expedite this process, we are making every effort to keep all internal components informed of the contents of the final rule as we progress. We anticipate publication of the final rule this winter with an effective date about four months after publication.

While the laboratory standards are undergoing Departmental review, we will be developing the guidelines, forms, and survey procedures to be used by the States and private organizations to implement the regulations. Our plan is to have these materials ready to go on the effective date of the laboratory standards.

User Fees

The law requires the costs of implementation, administration, and enforcement of the regulations to be paid by user fees from laboratories. The proposed rule specifies the application process and the methodology used to determine the amount of the fees. Laboratories will be required to obtain provisional certificates until they can be inspected to determine their compliance with the CLIA regulations. Under the proposed rule, these certificates will cost $261 and be valid for no more than two years.

Once the laboratory standards regulation is published, laboratories performing only tests on the waiver list will apply for the certificate of waiver. Under the proposed rule, these certificates will cost $156 every two years. A laboratory which is accredited by an HHS-approved accreditation program or State licensure program will apply for a certificate of accreditation. A laboratory which is surveyed directly by HCFA through the States will apply for a regular certificate. The cost of the regular certificate and the certificate of accreditation will be dependent on the number and type of tests the laboratory performs and is payable every two years.

The proposed user fee regulation generated 93 public comments which have been reviewed and analyzed. A draft of the final rule is under review. We expect it will be published in May or June 1991.

To implement the user fee rule, we have purchased a mailing list of laboratories from Dunhill Mailing Lists. Once the rule is published, we will notify approximately 640,000 potential laboratories about the rule and ask them to submit applications for provisional certificates. The applications will request information on the types and numbers of tests performed, the methodologies used, and the qualifications of the personnel performing laboratory tests and directing and supervising the laboratory.

We are contracting with private companies to handle the printing and mailing, collect fees, and enter the data from the applications into a computerized database. We expect this infrastructure to be operational when the final rule is published.

Accreditation

The proposed accreditation regulation specifies the conditions under which private, nonprofit accreditation organizations or State licensure agencies can qualify to approve laboratories. Accrediting bodies must have equivalent standards and use a survey process equivalent to the CLIA requirements.

A laboratory is deemed to meet all the CLIA program requirements if it passes the survey of an approved accrediting body. Deemed laboratories must agree to authorize the accrediting body to release to HCFA all records and information required by the regulation.

HCFA received 32 public comments in response to this proposed rule. The comments have been reviewed and analyzed and a draft of the final rule is being developed. We anticipate publication of the final rule in October 1991.

Enforcement

This proposed rule delineates the intermediate sanctions that HCFA can employ to enforce compliance with CLIA requirements. Intermediate sanctions may include a directed plan of correction, State onsite monitoring, or civil money penalties. Under certain conditions, HCFA may suspend or revoke a laboratory's CLIA certificate. Procedures for appeals are also specified in the proposed rule.

The proposed enforcement rule was published April 2, 1991 and the public comment period will close on June 3, 1991. We expect to publish the final rule this winter.

Conclusion

We share your concern that patients have assurances that their laboratory results are accurate. That is why HCFA included CLIA standards on proficiency testing and quality assurance for cytology in the final rule published March 14, 1990.

The four CLIA regulations have been a priority at both HCFA and the PHS. We have learned much from the comments and are making every effort to develop a workable approach to implementing the complexity model of regulation. We are optimistic that solutions to the complex technical issues can be found.

We have worked hard on these laboratory regulations and have made steady progress. The two most important regulations -- user fees and laboratory standards -- are on track. User fees will be published in the summer. Laboratory standards will follow in the winter. All the regulations will be published by early 1992.

Thank you. I am happy to answer any questions you may have.

Mr. DINGELL. Doctor, the committee thanks you for your very helpful testimony.

The Chair will recognize Dr. Roper. Doctor?

TESTIMONY OF WILLIAM L. ROPER

Mr. ROPER. Thank you, Mr. Chairman. It's a pleasure to be before your committee to discuss the important question of laboratory quality and how to improve it. As Dr. Wilensky has told you, CDC's primary role in this process is advising HCFA on technical and scientific issues in the area of the complexity model, cytology standards and proficiency testing standards.

In recent months, our major focus has been the review and tabulation of the many comments and suggestions received on last year's notice of proposed rulemaking. Analysis of the data and subsequent development of scientifically sound alternatives are currently underway.

We are collaborating with our colleagues in HCFA to develop alternatives to the present regulatory model. This task is expected to be completed by mid-summer and will be presented to the Secretary for a final decision shortly thereafter. We're making an honest effort with unprecedented resources to do our part in developing a final CLIA rule.

We do this in response to your Congressional mandates and in response to the many commentors who have stated that they believe that CLIA is unworkable. We will continue to deal with the scientific and technical issues and later this year, we will report to you on our progress in developing the final rule.

In order to complete the review of the thousands of letters in a timely and useful fashion, we developed a process which would give us a thorough description of their concerns and alternatives. We initiated this review with a highly qualified, but small technical staff.

Shortly thereafter, more technical staff were added and then through temporary hire and internal details, a large number of laboratory scientists and medical technologists were added to this process. On a parallel track, we also began recruiting and hiring permanent staff which we think are necessary for providing us with the scientific and technical expertise for developing alternatives to the proposed regulatory scheme, implementing a final rule and assisting with all the other scientific and technical CLIA-related tasks.

We began our review of the comments by looking at letters from 92 national professional organizations, but then went on to review the 35,000 letters received by HCFA representing nearly 60,000 individual signers. We especially focused on the 60,000 comments applicable to the complexity model, cytology and proficiency testing.

I would just add that this was not only a huge volume of comments, but many of them were quite extensive, hundreds of pages long. We've now completed the process of sorting the information, and are, as I said, beginning to develop alternatives.

Many important issues have been raised, and I'd like to just summarize the most significant ones with you. First, the complexity model:

CLIA '88 puts forth the model of regulation that is site-neutral; that is, it regulates tests in much the same way, no matter where that test is done. It's also based on the complexity of the test performed and the risk of harm to the patient if erroneous results are reported.

To implement this mandate, we, in conjunction with FDA and HCFA, recommended a complexity model with three categories, as have been described for you previously. In brief, the more complex a test and the greater risk to the patient, the more Federal regulation is required. We believe this is appropriately weighted towards protecting the interests of the persons being treated.

The following steps were taken in developing this model: collaboration among Federal agencies, then development of the criteria, largely by CDC and FDA, but also because this is the first time a national complexity model had ever been attempted, we asked for comment in the proposed rule and received that from large numbers of organizations, thousands of such comments.

Let me summarize the issues raised in those comments: the overwhelming majority of the comments we have received touch on this issue of complexity. It is important to understand that the complexity model has important implications for personnel, quality control, quality assurance and proficiency testing. Simply put, changing something here will inevitably change that part of the regulation.

Many commentors felt that the complexity model should not be applied to their specific situation. They sought exemption entirely. Others raised concerns over the use of and logic behind the model itself. Others recommended a revision of the model to address their concerns. Finally, others recommended that their tests be assigned to another category, a change in the specific categorization.

Let me turn now to the proficiency testing regulations: During 1987, CDC developed a uniform proficiency testing program in response to a request from HCFA. We held a public meeting in May of that year to discuss important proficiency testing issues and, along with HCFA, put forward a proposal in 1988 that would extend proficiency testing to all laboratories. That's what your law, the CLIA '88 did as well.

The issues raised in the comments on proficiency testing are, in sum, that there was too much emphasis placed in last year's NPRM on proficiency testing performance. Others said that we needed more scientific information. Indeed, that's why these studies required by CLIA '88 are so important.

Thirdly, let me turn to the cytology regulations. In March and September of 1988, CDC, HCFA and NIH sponsored conferences to obtain information for developing cytology quality control and proficiency testing standards. We advised HCFA on the development of a regulation that was proposed in August of 1988, on cytology testing.

In May of last year, this proposed regulation that we're here today talking about, proposed essentially these same standards for all laboratories subject to CLIA '88. In the comments that we just now received, the cytology issues have drawn considerable comment. Many commentors were concerned about the shortage of cytotechnologists and felt that these regulations would exacerbate that problem.

Others took issue with the requirement for individual proficiency testing twice each year and the 500-slide rescreen requirement following the failure of a proficiency test. Current providers of proficiency testing materials have expressed concern about the availability of referenced cytology material to implement a national proficiency testing program. Others raised concerns about the requirement for reporting premalignant and malignant diagnoses to State health departments, thinking it was too burdensome for the laboratory and suggested that the physician ought to do that.

Finally, the law, CLIA '88, required that a series of studies be undertaken by CDC to investigate further the many scientific and technical issues raised here. In compliance with that requirement, we undertook a comprehensive literature search to understand what the state of the art is in this area, and submitted that to you in a report in May of last year.

Also last year, we undertook a contract with Research Triangle Institute to develop a comprehensive research strategy for these studies and to develop design and implementation plans. We have completed the first phase of that process and are now into the second phase. We believe we will be able to develop requests for contracts to conduct those studies early next year and that these studies will take 2 to 5 years to complete.

I'm pleased with the progress that we've made on these studies, to date, but obviously, we have much more to do. Thank you. I'll be glad to respond to your questions.

[Testimony resumes on p. 93.]

[The prepared statement of Dr. Roper follows:]

Testimony by

William L. Roper, M.D.
Director
Centers for Disease Control
Public Health Service
U.S. Department of Health and Human Services

Good morning Mr. Chairman and members of the Subcommittee. I am Dr. William L. Roper, Director, Centers for Disease Control (CDC). I am pleased to testify before this Subcommittee on the subject of CDC's current activities in implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

As you know, administrative responsibility for CLIA '88 rests with the Health Care Financing Administration (HCFA). CDC's primary role is to provide technical and scientific support to HCFA in the areas of developing a complexity model, cytology standards, and proficiency testing standards for the final rule for CLIA '88.

In recent months, the major focus at the CDC has been the review and tabulation of the comments and suggestions received on the CLIA '88 Notice of Proposed Rule Making. Analysis of the data and subsequent development of scientifically sound alternatives are currently underway. CDC has convened internal PHS working groups to undertake a thorough analysis of the changes recommended by commenters. This is providing additional technical and scientific information for the development of the proposed alternatives. HCFA and PHS are collaborating to develop alternatives to the present regulatory model. This task is expected to be completed by mid-summer and will be presented to the Secretary for a final decision shortly thereafter. CDC will assist HCFA in drafting the proposed preamble and regulatory language for the complexity model, cytology standards, and proficiency testing standards. The draft rule will then be reviewed within the Department and by OMB.

We are making an honest effort with unprecedented resources to do our part in developing a final CLIA rule. We do this in response to your Congressional mandates in CLIA '88 and in response to the many commenters who have stated they believe that CLIA is unworkable. We will continue to deal with the scientific and technical issues, and later this year we will report to you on our progress in developing a final rule.

PROCESS TO REVIEW AND CODE COMMENTS

In order to complete the review of the thousands of letters in a timely and useful fashion, a process was developed which would give us a thorough description of the concerns, suggestions, and alternate proposals provided by the commenters. The responsibility for the review process was initiated with a highly qualified but very small technical staff. Shortly thereafter, a few technical staff were added, via detail from other CDC assignments, to complete development of the review and coding process. We then added, through temporary hire and internal details, a large number of laboratory scientists and medical technologists which we determined were essential to thoroughly review the thousands of comments within a relatively short time. On a parallel track we also began recruiting and hiring permanent staff which we think are necessary for providing us with the scientific and technical expertise for (1) developing alternative regulatory proposals, (2) implementing a final rule, and (3) assisting with all other scientific and technical CLIA-related tasks.

The approach taken to review and code comments was to begin with letters from 92 national professional organizations because we anticipated that the comments from those organizations would provide an early, comprehensive picture of the views of most commenters. We reviewed the 35,000 letters received by HCFA (representing nearly 60,000 individual signers) and tabulated approximately 60,000 comments from the 22,000 letters applicable to the complexity model, cytology, and proficiency testing.

As Dr. Wilensky noted, not only did the comment period for this proposed regulation result in a huge volume of submissions, but comments often included extensive technical information, scientific publications and references, and lengthy discussions of technical issues. We have now completed the process of sorting the information by regulation citation. Supporting data, provided with the comment or referenced by the commenter, has been abstracted and will be included in the analysis.

Many important issues have been raised in the comment process, and it would be impossible to cover all of them today. I will share some of the most significant ones which are of concern to national professional organizations, physicians and other health care professionals, and individuals.

I will discuss our activities related to the development of three areas of the regulation: the complexity model, proficiency testing, and cytology. Following discussion of each area, I will discuss major issues raised by commenters regarding that area.

DEVELOPMENT OF THE COMPLEXITY MODEL

Congress enacted a new schema for laboratory regulation in CLIA '88. The law required a model of regulation that is site neutral and based on the complexity of the tests performed and risk of harm to the patient if erroneous results are reported.

To implement the mandate, CDC in conjunction with FDA and HCFA recommended a complexity model with three categories of laboratory tests: (1) waivered tests which are simple to perform and pose no risk to the patient if erroneous results are reported. These tests require no regulation; (2) Level I tests which are moderately complex to perform and may pose some risk of harm to the patient if erroneous results are reported. These tests require standards for quality control/quality assurance, proficiency testing, and director and analyst personnel requirements; and (3) Level II tests which are complex to perform and may pose serious risk of harm to the patient if erroneous results are reported. This level includes all tests not contained in the waiver and Level I category and all new technology. In brief, the more complex a test and the greater risk to the patient following an erroneous result, the more federal regulation is required. The model was weighted toward protecting the interest of persons being tested, i.e., minimizing the potential for harm which might occur if persons receive an erroneous test result.

The following steps were taken in developing the model: (1) collaboration among CDC, FDA, Office of the Assistant Secretary for Health, HCFA, Office of the Secretary, and Office of Management and Budget; (2) development by CDC and FDA staff of criteria for the complexity model based on explicit language in CLIA '88 and consideration of the experience of several states which currently regulate physician office laboratories using some version of a complexity-based approach.

Because a national complexity model had never been attempted, we asked specifically in the preamble to the proposed rule for comment on a number of technical as well as policy elements of the proposal. Given the potential impact of this rule (300,000 - 600,000 laboratories) the Department expected, and indeed received, thousands of comments.

Under the currently proposed three-tiered complexity model, tests which are simple or of essentially negligible risk, even if performed incorrectly, are to be waivered, and laboratories performing only such tests are required simply to register and pay a nominal fee to HCFA.

Tests which are simple but carry a reasonable risk of harm to the patient if performed incorrectly are classified as Level I, a category which was thought at the time the NPRM was developed to include most of the tests currently performed in physician offices. Tests which are complex, which carry a serious risk of harm to the patient if reported erroneously, or which otherwise are not categorized in the waiver or Level I tiers, are classified as Level II.

MAJOR ISSUES RELATED TO THE COMPLEXITY MODEL

The overwhelming majority of the comments addressed issues related to the proposed complexity model. The complexity model, which formed the centerpiece of the proposed regulations, is based on the complexity of testing and risk of harm to patients of an erroneous result. In addition, the complexity model impacts on areas of the proposed regulation for personnel, quality control/quality assurance, and proficiency testing.

Many commenters felt that the complexity model, as currently constructed, should not be applied to their specific situation. In particular, providers in rural areas and in public health agencies raised significant concerns about the impact of the complexity model on access to quality medical care and vital prevention programs throughout the country. CDC, as the Nation's prevention agency, will be sensitive to these concerns, as well as to those expressed by the private sector.

Some commenters raised concerns over the use of and logic behind the complexity model itself. In general, they indicated that the regulations should consider factors other than test complexity and patient risk in determining requirements under the standards. The major additional factors relate to the type of test instrumentation used and the context under which testing is performed.

Further, many commenters recommended a revision of the complexity model to address their concerns. Finally, others recommended that tests assigned to one category be moved to another. A number of physicians expressed concern that the proposed CLIA '88 standards, in general, and the use of the complexity model approach, in particular, will compromise their ability to practice medicine and assure patient access to health care.

DEVELOPMENT OF PROFICIENCY TESTING REGULATIONS

During 1987, CDC developed a Uniform Proficiency Testing Program in response to HCFA's request for a single program that could be applied both to laboratories that receive Medicare reimbursement and those licensed under CLIA '67. On May 4, 1987, a public meeting was held to provide an opportunity for comments about the proposed uniform proficiency testing program. Based on comments received, a revised program was submitted by CDC to HCFA and became the basis for the proficiency testing requirements established in the final rule for the Medicare and CLIA '67 laboratories as published recently. The proposed CLIA '88 rule would extend these standards to all laboratories.

MAJOR ISSUES RELATED TO PROFICIENCY TESTING

In comments on proficiency testing as part of CLIA '88 -- that is, as they apply in ambulatory and non-hospital settings -- there is general concern that too much emphasis is being placed on proficiency testing performance as an outcome measure of overall laboratory performance. Commenters contend that if laboratories adhere to other requirements of the regulations (e.g., personnel, quality control/quality assurance provisions) the need to rely on proficiency testing to monitor laboratory performance is reduced. Therefore, they feel that the proficiency testing requirements should be reduced.

Some commenters also stated that the proficiency test requirements are not scientifically justified. Some made reference to the fact that the CLIA '88 legislation requires the Department to conduct studies on proficiency testing to address some of these scientific and technical issues. I will say more about those studies in a moment.

DEVELOPMENT OF THE CYTOLOGY REGULATIONS

CDC has long recognized the importance of developing quality standards for cytology performance based on sound scientific principles. In March and September of 1988 CDC, HCFA, and NIH sponsored conferences to obtain information for developing cytology quality control and proficiency testing standards. The information from these meetings, and CDC's previous experience with self-evaluation studies in cytology, guided CDC in the development of proposed standards for cytology proficiency testing and quality control/quality assurance for laboratories subject to regulation under Medicare and CLIA '67. These standards were first published in the August 5, 1988, NPRM for Medicare and CLIA '67 laboratories.

In May 1990 essentially the same standards were proposed for laboratories subject to CLIA '88. Specific Congressional guidance (e.g., workload limitations) was included in the CLIA '88 law and was incorporated into the NPRM for CLIA '88 laboratories. In addition, comments received from the August 5, 1988, NPRM were used to revise the standards for CLIA '88. We anticipate further revision based on the analysis of the comments from the proposed rule for CLIA '88.

MAJOR ISSUES RELATED TO CYTOLOGY

The national cytology standards called for in the CLIA '88 Act and the proposed regulation to implement these standards have drawn considerable comment. A major concern of most commenters is that the stringency of the proficiency testing and quality control/quality assurance requirements will exacerbate the shortage of cytotechnologists and further limit the access to care. In particular, the commenters cite, as excessive and burdensome, the requirements of individual proficiency testing twice per year and the 500 slide re-screen following a failure in a proficiency testing event.

Physicians and technologists have expressed concern about the requirement for screeners (i.e., the cytotechnologists) and interpreters (i.e., the physicians) to be tested and graded in the same manner on proficiency testing events since their responsibilities in the testing process are vastly different.

Current providers of proficiency testing materials have expressed concern about the availability of referenced cytology material to implement a proficiency testing program nationally. Finally, commenters expressed major concern that the requirement for reporting pre-malignant and malignant diagnoses to state health departments is too burdensome for the laboratory and should be the responsibility of the physician. Further comments indicated that many states do not have a mechanism or the resources to accept and manage these results.

THE CLIA '88 STUDIES

CDC has the responsibility for conducting the 5 studies mandated in Section 4(a) of CLIA '88. The studies represent the core of research needed (1) to establish the link between regulatory requirements (proficiency testing performance, personnel qualifications, and internal quality control and quality assurance) and the reliability and accuracy of laboratory test results; (2) to determine the extent and nature of problems in the diagnosis and treatment of patients caused by inaccurate test results; and (3) to determine which steps in the total testing process are most error prone and how these errors influence the overall accuracy of patient results.

Getting these studies underway has proven difficult because of the breadth of the questions posed. In order to summarize the findings from previously conducted research relative to the answers sought in the CLIA '88 studies, a comprehensive literature search was conducted by CDC. A summary of the results was included in a report submitted to Congress in May 1990, along with a description of the process that CDC proposed to use to develop sound scientific studies.

On September 30, 1990, a contract was awarded to the Research Triangle Institute to develop a comprehensive research strategy for the studies and to develop design and implementation plans. The research strategy, the first phase of the contract, was evaluated by CDC staff and an external panel of laboratory scientists who served as consultants to CDC. The first phase was completed on March 28, 1991. The resultant strategy includes a recommendation for surveys of national samples of laboratories and physicians.

The final design and implementation plans for the studies are scheduled to be presented to CDC by Research Triangle Institute on December 31, 1991. As in phase I, CDC will use consultants in phase

II to assist in evaluating certain areas. We expect to develop Requests for Contracts to conduct the studies in early 1992. Based on the strategy proposed in phase I, we estimate that the studies will take two to five years to complete.

I'm pleased with the progress that we have made to date. When the user fees authorized under the Act are collected, we will be able to make even greater progress on these studies.

In conclusion, I'm pleased to provide to the Subcommittee a timetable which describes the tasks conducted to complete this process. Further, as requested, we are providing more detailed information on staffing, contractual matters, and communications regarding CLIA '88 standards, including those with the Office of Management and Budget.

This concludes my testimony. I will be happy to answer any questions you or other Members of the Subcommittee may have.

Mr. DINGELL. Thank you, Dr. Roper. Mr. MacRae we welcome you to the committee. You are recognized for such statement as you choose to give.

TESTIMONY OF JAMES B. MacRAE, JR.

Mr. MACRAE. Thank you, Mr. Chairman. This is the second time in these many days that I am in this room. Thank you for your invitation to testify. I welcome this opportunity to discuss OMB's role in the Department of Health and Human Services proposed rulemakings, implementing the Clinical Lab Improvement Amendments of 1988. In my statement, I will respond to the questions contained in your invitation to testify.

Item one, the time table for the Office of Management and Budget's receipt of the four regulations implementing the Clinical Lab Improvement Amendments '88 and OMB's approval of the regulations for publication.

Two, the methodology utilized by the OMB in reviewing the proposed regulations, any alterations required by OMB prior to approval for publication, and the chronology of those activities.

Item three, a discussion of the September 21, 1990 comments on the proposed regulations submitted by OMB to the Health Care Financing Administration.

Item four, the OMB's position on Congressionally mandated deadlines imposed by the '88 Act.

As to the time table for OMB Executive Order 12291 review, the Department determined that four rules must be promulgated as proposed and final to fully implement CLIA '88, as enacted on October 31, 1988. The subject of each of the four rules follows, and I do not really need to repeat them here. We all know what they are.

The Department has published all four of these rules, as proposed in the Federal Register. We reviewed each of these rules under the executive order. The chronology for OMB's receipt and completion of review of these rules is provided in attachment A to my testimony that was submitted. This chronology provides the title of the rule, the date the rule was received for OMB review, the date review was concluded by OMB and the publication date.

OMB's review of each of these rules was completed in an average time of 41 days. In particular, the OMB review of the proposed rule establishing uniform standards for all laboratory sites was completed in 22 days. This rule raised the ground work for the rules that follow and, in many respects, determines the user fee, deeming policies and enforcement policies.

Pursuant to the Executive Order 12291, OMB reviews agencies proposed and final rules prior to publication in the Federal Register. The methodology used by OMB to review all rules submitted pursuant to the Executive 12291, consists of the following: We log in the rule, we distribute it to OMB analysts responsible for reviewing the submissions affecting a particular program or agency. Our analysts read the rule to determine whether it meets the criteria of 12291. They have identified the provisions in the rule that raise concerns pursuant to the Executive Order or other OMB oversight's responsibilities, such as the Paperwork Reduction Act. Point four. Other analysts in OMB are consulted to lend their program or analytic expertise, if there are questions regarding the rules effects on other programs or a more detailed analysis is needed. Finally, as a result of the coordinated analytic review, the OMB desk officer determines what questions should be discussed with the Agency.

In most cases, after completing its analysis, OMB raises questions and makes recommendations to agencies, regarding the rule under review. It is important to note that OMB cannot require agencies to accept recommendations. Ultimately, as section 3.F and 3.F3 and 8A2 of the Executive Order 12291 make abundantly clear, the final decisions on the provisions of all rules rests with the agencies.

Upon receipt of each of the four proposed rules, OMB proceeded with its review, pursuant to criteria outlined in the Executive Order. In the course of our review of these particular rules, we emphasized the following two criteria. The Department should choose regulatory objectives that would maximize net benefits to society. Among the alternative approaches to each regulatory objective, the Department should choose the alternative involving the least net cost to society.

In addition, the Executive Order categorizes as major, those rules imposing annual society costs of $100 million or more. The order requires agencies to prepare a regulatory impact analysis for all major rules. The regulatory impact analysis should identify the benefits and costs to the different entities affected by the rule. On the basis of discussions with OMB, the Department agreed to categorize the proposed standard rules as major and to perform a regulatory impact analysis. Because the Department had already fallen behind in its implementation of CLIA '88, OMB waived the regulatory impact analysis requirement for all of the implementing rules at the proposed rule stage.

The main modifications made by HCFA, after consideration of OMB's comments, are summarized in attachment B of my submitted testimony. Most of these modifications were additional language, in the preambles, that discuss possible alternatives to the requirements in the rules and solicited public comment on particular provisions in the rules. Regarding the text of the proposed rules, OMB deferred to the Departments experts in the Health Standards Quality Bureau at HCFA, the Centers for Disease Control and the Food and Drug Administration.

Regarding our public filing, we expeditiously reviewed the rule, that is the implementing rule, and filed our own public comment on September 21, 1990. Attachment C contains a copy of that comment. In many instances, in order to insure that there is no delay of a rule, especially when the rule raises important economic and policy concerns, OMB has and will continue to file a public comment on a proposed rule.

In this instance, OIRA developed its arguments and articulated its concerns, on the basis of its knowledge of the programs, common economic principles, and the absence of supporting evidence from the Department for its selected policy approaches. Many of the concerns raised in our public filing are echoed in the extensive public comments and some of the more technical recommendations are built on concerns raised in the many comments OMB received.

Our public filing expresses significant concerns regarding the proposed standard rules, implications for quality of care, access to care and cost containment. We were particularly interested in the trade-offs between enhanced quality, access and cost. For example, the rising costs could lead to the closure of labs and delayed testing for indigent and disabled populations. Test delayed or not taken may have the same effect as a false negative test result and may have implications for patient health status.

We recommended that the Department closely evaluate and understand these trade-offs prior to development of its final policies. If such trade-offs are ignored, the final standards may generate outcomes inconsistent with Congressional intent.

Now, with regard to our position on statutory deadlines, I wish to say categorically, that we obey the law and we, in no way would do anything to delay the promulgation of a regulation beyond any statutory or judicial deadlines. We have reviewed these four rules in a timely fashion, an average of 41 days. We waived the regulatory impact analysis requirement at the proposed rule stage, to facilitate prompt issuance of these rules.

Thank you for inviting me to testify. I will be glad to answer any questions, Mr. Chairman.

[Testimony resumes on p. 117.]

[The prepared statement and attachments of Mr. MacRae follow:]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

STATEMENT OF JAMES B. MACRAE, JR.
ACTING ADMINISTRATOR
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
BEFORE THE OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
CONCERNING IMPLEMENTATION OF THE
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988
MAY 2, 1991

Mr. Chairman, thank you for your invitation to testify. I welcome this opportunity to discuss OMB's role in the Department of Health and Human Services' proposed rulemakings implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). In my statement I will respond to the questions contained in your invitation to testify:

1. The timetable for the Office of Management and Budget's (OMB) receipt of the four regulations implementing the Clinical Laboratory Improvement Amendments of 1988 and the OMB's approval of the regulations for publication;

2. The methodology utilized by the OMB in reviewing the proposed regulations, any alterations required by the OMB prior to approval for publication, and the chronology of those activities;

3. A discussion of the September 21, 1990, comments on the proposed regulations submitted by the OMB to the Health Care Financing Administration; and

4. The OMB's position on Congressionally-mandated deadlines imposed by the 1988 Act.

Timetable for OMB Executive Order No. 12291 Review

The Department determined that four rules must be promulgated in final to fully implement CLIA '88 as enacted on October 31, 1988. The subject of each of the four rules follows:

1. Uniform proficiency testing, quality assurance and personnel standards for all laboratory sites (commonly referred to as the "standards rule");

2. Industry user fees covering the cost of CLIA '88 implementation (commonly referred to as the "user fee rule");

3. General criteria for granting deemed status to certain organizations (commonly referred to as the "deeming rule"); and

4. Intermediate enforcement sanctions (commonly referred to as the "enforcement rule").

The Department has published all four of these rules as proposed in the Federal Register. OMB reviewed each of these rules under Executive Order No. 12291 (E.O. No. 12291). The chronology for OMB's receipt and completion of review of these rules is provided in Attachment A to my testimony. This chronology provides the title of the rule; the date the rule was received for OMB review; the date review was concluded by OMB; and the publication date.

OMB's review of each of these rules was completed in an average of time of 37 days. In particular, the OMB review of the proposed rule establishing uniform standards for all laboratory sites was completed in 22 days. This rule lays the ground work for the rules that follow and in many respects determines the user fees, deeming policies, and enforcement policies.

Methodology Used in OMB Review

Pursuant to E.O. No. 12291, OMB reviews agency proposed and final rules prior to publication in the Federal Register. The methodology used by OMB to review all rules submitted pursuant to E.O. No. 12291 consists of the following: (1) the rule is logged in and distributed to the OMB analysts responsible for reviewing submissions affecting a particular program or agency; (2) the analysts read the rule to determine whether it meets the criteria of E.O. No. 12291; (3) they identify the provisions in the rule that raise concerns pursuant to E.O. No. 12291 or other OMB oversight responsibilities, such as the Paperwork Reduction Act; (4) other analysts in OMB are consulted to lend their program or analytical expertise if there are questions regarding the rule's effects on other programs or more detailed analysis is needed; and (5) as a result of this coordinated analytical review, the OIRA desk officer determines what questions should be discussed with the agency.

In most instances, after completing its analysis, OMB raises questions and makes recommendations to agencies regarding the rule under review. It is important to note that OMB cannot require agencies to accept recommendations. Ultimately, as Sections 3.(f)(3) and 8.(a)(2) of E.O. No. 12291 make abundantly clear, the final decisions on the provisions of all rules rest with the agencies.

Upon receipt of each of the four CLIA proposed rules, OMB proceeded with its review pursuant to criteria outlined in the Executive Order. In the course of its review of these particular rules, OMB emphasized the following two E.O. No. 12291 criteria:

- The Department should choose regulatory objectives that would maximize net benefits to society; and

- Among the alternative approaches to each regulatory objective, the Department should choose the alternative involving the least net cost to society.

In addition, the Executive Order categorizes as major those rules imposing annual, societal costs of $100 million or more. The Order requires agencies to prepare a Regulatory Impact Analysis (RIA) for all major rules. The RIA should identify the benefits and costs to the different entities affected by the rule. On the basis of discussions with OMB, the Department agreed to categorize the proposed standards rule as major and to perform an RIA. Because the Department had already fallen behind in its implementation of CLIA '88, OMB waived the RIA requirement for all of the implementing rules at the proposed rule stage.

The main modifications made by HCFA after consideration of OMB's comments are summarized in Attachment B. Most of these modifications were additional language in the preambles that discussed possible alternatives to the requirements in the rules or solicited public comment on particular provisions in the rules. Regarding the text of the proposed rules, OMB deferred to the Department's experts in the Health Standards Quality

Bureau at the Health Care Financing Administration, the Centers for Disease Control, and the Food and Drug Administration (FDA).

Examples of these kinds of modifications and the most extensive such modifications made during OMB review were in the preamble of the standards rules. In the course of its review, OMB recommended that the Department amend the RIA statement to acknowledge the rule constituted a major rule pursuant to E.O. No. 12291 and to include questions regarding available data and information on measurable benefits in test accuracy and decreases in morbidity and mortality. OMB recommended soliciting public comment on the relationship between personnel credentialling and test accuracy. In addition, OMB recommended soliciting public comment on the cost effectiveness of computer quality assurance requirements and application of such requirements exclusively to automated systems as opposed to manual systems. OMB also recommended soliciting comment on special emergency exemptions for areas that may suffer from decreased access. OMB recommended that the Department clarify its deeming policies and commit to the establishment of deeming criteria pursuant to CLIA '88. Finally, OMB recommended soliciting comment on the difference between the categories of test complexity in the proposed rule and FDA's classification of clinical chemistry and clinical toxicology devices or any testing methods that are subject to FDA approval pursuant to the Food Drug and Cosmetic Act.

OIRA's Public Filing

The Office of Information and Regulatory Affairs (OIRA) expeditiously reviewed the rule and filed its own public comment on September 21, 1990. Attachment C contains a copy of this comment. In many instances, in order to ensure there is no delay of a rule, especially when the rule raises important economic and policy concerns, OIRA will file a public comment on a proposed rule. In this instance OIRA developed its arguments and articulated its concerns on the basis of its knowledge of the programs, common economic principles, and the absence of supporting evidence from HHS for its selected policy approaches. Many of the concerns raised in OIRA's public filing are echoed in the extensive public comments and some of the more technical recommendations build on concerns raised in the many comments OMB received.

OIRA's public filing expresses significant concerns regarding the proposed standards rule's implications for quality of care, access to care, and cost containment. The main quality concerns focused on: whether the chosen personnel and proficiency standards would result in any significant increase in test accuracy; whether the improved test accuracy would result in significant improvement in health status; and, if potential negative impacts on quality resulting from decreased access or barriers to bedside testing technologies may offset quality improvements.

OIRA particularly is interested in the trade-offs between enhanced quality, access, and cost. For example, rising costs could lead to the closure of labs and delayed testing for indigent and disabled populations. Tests delayed or not taken may have the same effect as a false negative test result and may have implications for patient health status. OIRA recommended that the Department closely evaluate and understand these trade-offs prior to development of its final policies. If such trade-offs are ignored, the final standards may generate outcomes inconsistent with Congressional intent.

OMB's concerns about cost containment should come as no surprise to Congress and seem to be concerns shared by the Administration and Congress. In the face of spiralling health care costs and efforts to expand health care coverage to the uninsured, it is clear we should be interested in making the CLIA '88 implementing rules as cost-effective as possible.

In addition to these broader concerns, our filing raised questions regarding the following: the breadth of the rule's definition of laboratory; the differences between the test complexity categories and FDA's device classification and how the same tests get classified under each scheme; the use of costly prescriptive requirements in addition to outcome requirements; and the need for an RIA.

OMB's Position on Statutory Deadlines

OMB's position regarding Congressionally-mandated deadlines imposed by CLIA '88 is that they are the law and, of course, must be adhered to like any other law. OMB ensures that no actions taken by OMB will cause an agency to miss these deadlines. In this instance, the rules were reviewed in a timely fashion -- an average of only 37 days, and we waived the RIA requirement at the proposed rule stage to facilitate prompt issuance of the rules.

Closing Remarks

Thank you for inviting me to testify this morning. I would be happy to answer any of your questions.

ATTACHMENT A

Chronology of OMB Review
CLIA '88 Proposed Rules

1. "Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (Medicare and Medicaid)" HSQ-176-P

Receipt: 04/19/90. **Review Concluded:** 05/11/90.
Publication: 05/21/90.

2. "Clinical Laboratory Improvement Amendments of 1988; Fee Collection" HSQ-177-P

Receipt: 07/10/90. **Review Concluded:** 07/26/90.
Publication: 08/03/90.

3. "Granting and Withdrawal of Deeming Authority to Private Non Profit Accreditation Organization and State Licensure Agencies" HSQ-181-P

Receipt: 07/10/90. **Review Concluded:** 07/26/90.
Publication: 08/20/90.

4. "Enforcement Procedures for Laboratories" HSQ-179-P

Receipt: 11/05/90. **Suspension of Review:** 02/08/91. **Resubmission:** 03/22/91. **Review Concluded:** 03/22/91. **Publication:** 04/02/91.

ATTACHMENT B

OMB E.O. No. 12291 Alterations
CLIA '88 Proposed Rules

Title: "Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (Medicare and Medicaid)" HSQ-176-P.

Significant Alterations

o Reclassification of the rule as major and commitment to performance of a regulatory impact analysis (RIA).

o Amend the discussion of the RIA to include questions regarding the impact of the rule in terms of measurable benefits and costs, e.g. implications for test accuracy in terms of false negatives and positives, effect on mortality and morbidity, etc.

o Amend the RIA discussion to solicit comment regarding the benefits and costs of the cytology requirements, particularly in quality assurance.

o Amend the preamble to solicit comment on available data regarding the relationship of personnel credentialling to test accuracy and other benefits. The Department should commit to pursuit of the Section 4 studies in this area.

o Amend the preamble to solicit comment on the overlap and need for coordination between the FDA device classification system and the proposed test complexity model.

o Amend the preamble to solicit comment on the cost effectiveness of the proposed computer quality assurance standards and the application of such standards for automated but not manual systems.

o Amend the preamble to solicit comment on emergency waivers in circumstances demonstrating limited access to laboratory testing.

o Amend the preamble to clarify policies in regard to deemed status for accrediting groups, and commit to establishment of criteria for deeming pursuant to CLIA '88.

Department Changes: 05/08/90, 05/10/90, and 05/11/91.

Title: "Clinical Laboratory Improvement Amendments of 1988; Fee Collection" HSQ-177-P.

Significant Alterations

o Amend the preamble to commit to: 1) thorough review of all public comments concerning the paperwork/application requirements and 2) consideration of comments in the design of an application for provisional certificates. Such an application should have standard definitions and instructions and be submitted to OMB for PRA review.

o Amend the preamble to solicit comments on the definition of a test and its feasibility, particularly in the area of quantitative testing.

o Amend the preamble in several places to clarify and describe historical, survey data used to set fees.

o Amend the RIA statement's assumption that many labs currently conduct proficiency testing and therefore, would not be affected by the provisions of the rules.

o Amend the preamble to solicit comment on the methodology, process, and schedule for revising fee breakouts by a laboratory's scope and volume of testing.

o Commit to analysis of costs imposed by the standards on the certification and inspection processes. Such an analysis would be presented in the RIA of the final standards rule.

o Amend the RIA statement's assumption that there will be improved quality of care.

o Amend the RIA statement's assertion regarding the percentage cost increase resulting from the user fees.

o Amend the RIA statement to generally solicit public comment on the costs and benefits of the user fee rules, and commit to analysis prior to issuance of a final rule.

Department Changes: 07/23/90 and 07/24/90

Title: "Granting and Withdrawal of Deeming Authority to Private Non Profit Accreditation Organization and State Licensure Agencies" HSQ-181-P.

Significant Alterations

o Amend the preamble to solicit comment on the extent to which the new requirements imposed by the deeming rule and standards rule would affect pricing schemes of accreditation organizations.

o Amend the language in the RIA statement assuming that rule's impact on accrediting groups and labs paying fees to such groups would be less than $100 million annually.

o Amend proposed code mandating an annual report to House Committee on Energy and Commerce and Senate Committee on Labor and Human Resources. The report is mandated by CLIA '88 and is self implementing.

Department Changes: 07/30/90

Title: "Enforcement Procedures for Laboratories" HSQ-179-P.

Significant Alterations

o Amend the preamble to solicit comment on immediate imposition of civil monetary penalties without a hearing.

o Further delineate the information to be provided in the annual lab registry and provide information on lab success in addressing deficiencies and improving performance.

o Amend the preamble to clarify the Department's rationale as to why poor performance under the proposed proficiency testing scheme should not be classified as immediate jeopardy.

OMB Discussions and Suspension of Review: 02/08/91.

ATTACHMENT C

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

SEP 21 [illegible]

Dr. Gail R. Wilensky
Administrator
Health Care Financing Administration
Department of Health and
Human Services
Washington, D.C. 20201

RE: Proposed Rule Pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88)

Dear Dr. Wilensky:

On May 21, 1990 the Department of Health and Human Services (HHS) published in the Federal Register a proposed rule entitled "Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88)." HHS was given the ambitious task of improving the accuracy of laboratory testing nation-wide. We recognize the difficulty of this task and submit these comments to the public record for your consideration and to aid you in this task.

We share Congress' objective of improving the health status of this nation. Efficient allocation of Federal resources also is a major concern, because our health care goals are unmet yet our resources are limited. We are equally concerned with the private sector costs of Federal health regulation and their implications for health care services. Pursuant to Executive Order No. 12291, agencies must ensure that their "regulatory objectives are chosen to maximize the net benefits to society." It is not clear that the proposed rule meets this criterion.

The United States health care delivery system is extremely complex. There are many tiers of service delivery that involve numerous medical professionals, industries, and protocols. In order to achieve its objective of improving the accuracy of laboratory testing, this rule must take into account these various components of the health care delivery system. This is particularly difficult to accomplish because very little data is available on how these various components interrelate to form the health care system.

We believe that improvements in the accuracy of lab testing can be achieved, but often at the cost of other desirable outcomes in health care delivery. We are concerned that some of the requirements of the proposed rule may not be consistent with the Administration's objectives in improving our nation's health care delivery systems.

The Administration's Agenda

On January 31, 1990, in his State of the Union Address, the President articulated three areas to be addressed when formulating policies for improving the nation's health care system: quality of care, accessibility of care, and cost containment. In the case of laboratory services, as with other health care services, these three concerns are inextricably linked.

QUALITY OF CARE

Improved quality of care is always desirable, but it cannot be pursued without regard for its costs. It is unclear that in the long term, improvements in quality of care through increased accuracy of test results will be achieved by the proposed implementing rule. The primary dilemma facing the Health Care Financing Administration (HCFA) is that adequate information is not available on improving accuracy of current lab testing.

Although performance standards such as proficiency testing are desirable approaches to regulating laboratories, certain proficiency testing outcomes may not clearly reflect the realities of laboratory testing. For example, in some instances the rigor of proficiency passing requirements for a given analyte are simply unrealistic. The regulation does not take into account the wide variability of tested samples. The data from Centers for Disease Control (CDC) used by HCFA to select the 80 percent passing level for pap smear, qualitative testing demonstrate that, depending on the difficulty of the slide, as many as 98 percent of CDC technicians would have failed.

In CLIA 88 Congress recognized the lack of data in these areas and required that the Public Health Service conduct studies of the "validity, reliability, and accuracy of proficiency testing" as well as the correlation between personnel and quality assurance standards and accuracy of laboratory test results. These studies have not been completed, and to OIRA's knowledge, have not been initiated.

Also, the rule appears to have been crafted as if the goal of health care quality could be pursued without due consideration for cost containment and access. There are risk-risk trade offs in the pursuit of quality. A decision not to be tested because of distance or cost barriers or delayed access to laboratory testing and physician diagnosis can have the same effect, e.g., delaying treatment, as a false negative test result.

Finally, the proposed rules have implications for research and development of health technologies and in the longer term may have deleterious effects on the health status of the nation. The laboratory of the future could be at each individual's bed side. For years, it has been our policy to encourage medical self-sufficiency and preventive health care, and to minimize health care costs by using the lowest cost means that do not compromise care. However, increases in prices, inappropriate requirements placed on automated devices, and laboratory closures due to this rule may result in the opposite. Testing performed in physician offices, home health settings, and hospices may be severely restricted or eliminated. Consequently, care that requires certain tests, particularly periodic tests, may be pushed into more traditional and costly health care settings.

Moreover, without this market, research and development into devices that facilitate preventive health and bedside care will slowly evaporate. Many of these devices have the potential to enhance quality of care, access to care and save health care dollars at the same time.

ACCESS TO LABORATORY TESTING, DIAGNOSIS AND TREATMENT

Increased cost of laboratory services will result in higher prices for services, and in some cases may result in laboratory closures. It is likely that closures will be more prevalent for labs serving rural populations and Medicaid recipients.

It is ironic that Medicaid recipients and lower income individuals are the same individuals that need to be encouraged to use screening services. Use of emergency room services is a chronic problem in the Medicaid program and is more expensive than preventive care. Laboratories performing tests to screen for anemia in the Women, Infants and Children (WIC) program have expressed concern that such services would no longer be affordable. As a result of regulatory costs imposed by personnel and quality assurance provisions, Planned Parenthood Clinics in New York City expect to suffer backlogs in reading cytology slides. In addition, public comments from personnel groups affirm that proposed credentialling requirements may have deleterious effects on the labor market and access to lab testing. Some groups argue that credentialling, at a minimum, should be grandfathered.

Rural closures may be a problem for Medicare patients, particularly those who are disabled. Medicare beneficiaries comment that travelling beyond the physician's office for lab tests and results would be costly or impossible for the physically disabled or ill. Some physicians have estimated that if closure is necessary, some patients may have to travel 200 to 300 miles to the nearest lab for testing. At best, the additional cost and possible closures will result in delays in diagnosis and treatment, or in worst cases, not being treated at all.

COST CONTAINMENT

Currently United States health care expenditures are growing at a rate exceeding that of our gross national product. From a Federal perspective, this development is most perplexing in the Medicare and Medicaid programs, which are being hard hit by aging demographics and demands by the low income and minority populations in areas such as drug abuse, AIDS, and infant mortality.

We are concerned that on top of these already escalating costs, the personnel, quality control, and proficiency testing provisions in the CLIA 88 rules may add requirements that will impose significant, additional costs on clinical laboratories without these commensurate benefits. In addition to expending additional resources to meet these new standards, laboratories will have to pay user fees to finance their own Federal survey and certification.

Three provisions predominantly affect the cost of this rule: 1) the scope of the proposed rule; 2) the complexity of test model; and 3) prescriptive regulatory approaches for each level of complexity.

Scope of the Proposed Rule

The Department engaged in little interpretation of the statutory definition of a laboratory. CLIA 88 defines a laboratory as a facility which examines "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." This definition in the broadest terms, includes law enforcement laboratories, drunk driving breathalizer tests, screening services for the poor offered in the WIC program, mobile cholesterol public screening services, in addition to the unregulated population of physician office labs. Direct cost implications are complicated by other considerations such as delays in criminal prosecution of drug traffickers and drunk drivers and decreased access to preventive services for the poor. Though we have not estimated the costs associated with this definition, we anticipate that they could be significant.

Complexity of Test Model

The Department's design of the complexity model and its classifications for each laboratory test greatly contribute to the cost imposed by these rules. The three tiered complexity model (waived tests, Level I, and Level II) establishes separate approaches to regulation. Each approach addresses personnel standards, quality assurance, and proficiency testing in different ways and with varied cost implications. Some of the specifics of these standards are required by statute; others resulted from HHS discretion.

The statute requires the Secretary in developing standards for laboratory test regulation, to take into account: 1) the examinations and procedures performed and the methodologies employed; 2) the degree of independent judgment involved; 3) the amount of interpretation involved; 4) the difficulty of the calculation involved; 5) the calibration and quality control requirements of the instruments used; 6) the type of training required to operate the instrument used in the methodology; and 7) such other factors as the Secretary considers relevant.

In addition to the above criteria, the Secretary must consider one other major requirement for a test tc be considered "simple" enough to be waived. The test must be a simple laboratory procedure which, as determined by the Secretary, has an insignificant risk of an erroneous result. These tests include those which have been approved by the Food and Drug Administration for home use; employ methodologies that are so simple that likelihood of erroneous results are negligible; or pose no reasonable risk of harm to the patient if performed incorrectly.

In selecting tests for each of the three categories for regulation, HCFA placed heavy emphasis on the risk to the individual patient of an erroneous result. This emphasis was made at the expense of considering the test methodologies and technologies, type of training required to conduct the tests, and other factors.

These classifications also do not consider erroneous test results in the context of the entire patient delivery system. In particular, there is very little data on how physicians interpret, diagnose, and recommend treatment from test results. As a result of this heavy emphasis on risk to the individual patient, HCFA decided that many tests, including glucose monitoring, should not be on the waived test list. In addition, without any clear distinctions, some comparable tests appear on the Level II complexity list rather than the Level I list, subjecting certain labs and individuals to higher levels of regulatory burden.

Also, the Department made little effort to coordinate the existing Food and Drug Administration device labelling scheme with the proposed rule's approach. Less cost would be imposed on research and development if clinical labs were subject to one set of consistent Federal criteria and classifications.

Prescriptive Regulatory Approaches

The regulation specifies three approaches to improving test accuracy in clinical laboratories: personnel standards, proficiency testing, and quality assurance. The most cost effective approach to regulating generally is based on performance standards that are clearly described in terms of desired objectives. Requirements that describe the means of achieving a goal are more costly and less effective. Therefore, to the maximum extent practical, it would have been preferable to emphasize proficiency testing in this regulatory scheme.

In regard to personnel standards, the statute requires that laboratories use only "personnel meeting such qualifications as the Secretary may establish. . . ." The statute does not specify detailed personnel standards. Costs imposed by the regulation's standards depend upon the Department's discretion and are the rule's most burdensome. For example, hiring an additional technician for each regulated physician office lab alone could cost \$3 to \$6 billion per year. This estimate is based on an assumption that 150,000 to 300,000 laboratories will hire an additional technician at a minimum cost of \$19,822 per year (current average salary of a medical laboratory technician). This estimate is not adjusted to account for laboratory closures due to costs of adopting these standards.

In the area of quality assurance, requirements such as the rereview of negative cytology slides demand additional technician manpower and resources. These and other quality assurance provisions also can delay test results. Direct costs of these provisions and indirect costs of delay could add another \$2 to \$4 billion per year. This estimate is based on one lab's comments estimating that these costs would be a minimum of \$10,000 per year, and assuming that these costs would affect from 200,000 to 400,000 labs per year.

Although performance standards tend to produce benefits more efficiently, it is important to note that the method for measuring performance can impose costs. For example, requiring five rather than two challenges per analyte, and sanctioning entire specialties impose additional cost on physician and hospital-based laboratories. Also, though the statute does not stipulate the methodology for proficiency testing, it mandates testing a minimum of twice per year, regardless of resource constraints or prior history of lab performance. These new provisions could cost as much as \$800 million to \$1.6 billion annually. This estimate assumes the cost of such provisions will be at least \$4,000 per year for a range of 200,000 to 400,000 laboratories. The \$4,000 figure is based on an industry estimate.

The above estimates clearly indicate that this proposed rule is major pursuant to Executive Order No. 12291 and requires a regulatory impact analysis (RIA). Prior to submission of the final rule for Executive Order No. 12291 review, the Department should submit an RIA evaluating the costs and benefits of the statute and the regulation. In addition, to assessing costs and benefits of the chosen approach for the rule, the Department's RIA should consider policy alternatives achieving the objectives of improved test accuracy at a lower net cost to society. These alternatives should include proposals that would require statutory change, if such proposals could achieve equal or greater benefits at a lower cost to society.

Recommendations

The previous sections outline general concerns with the proposed regulation. Admittedly, they do not offer tangible solutions. We believe, however, that prior to proposing solutions, it is important to understand the implications of those actions on the Federal government and private sector. Therefore, we remind you of our decision that pursuant to Executive Order No. 12291, your agency must conduct a thorough regulatory impact analysis prior to the submission of your final rules. In addition, we urge that you complete the studies mandated by Section 4 of CLIA 88.

To date, we have been unable to review the voluminous comments sent directly to OMB. However, we have forwarded all comments to the Department for consideration in the development of the final rule. In the meantime, we have identified several areas for HCFA's special attention during their review of the comments and the development of the final rule. We have enclosed an appendix that outlines these areas for potential change.

Thank you for your thoughtful consideration of our concerns. If you or your staff have any questions regarding these comments we would be pleased to discuss them further.

Sincerely,

James B. MacRae, Jr.
Acting Administrator and
Deputy Administrator
Office of Information and
Regulatory Affairs

Enclosure

c: Robin Carle

APPENDIX
Recommendations for HCFA's Consideration

- Waive glucose monitoring tests and conduct a comprehensive reassessment of Level I and Level II classification of all tests that are routinely performed in physician office labs and home settings, or utilize a technology that has little or no room for error.
- Reevaluate the requirement that a board certified pathologist or PhD serve as director of a Level II laboratory.
- Reevaluate the requirement that abnormal Level I screening test results for a previously undiagnosed condition be referred to Level II laboratories.
- Grandfather credentialling for competent technologists.
- Replace the 10 percent rescreen requirement for cytology quality assurance and 500 slide reexamination requirements with more cost effective approaches.
- Replace prescriptive quality assurance requirements for testing devices with reliance on manufacturer protocols.
- Delete costly computer system quality assurance requirements.
- Coordinate lab test/device classifications with Food and Drug Administration classifications and approvals of new devices.
- Provide information and findings on all HCFA research activities pursuant to Section 4 of CLIA 88.

Mr. Dingell. Thank you, Mr. MacRae. The Chair has a few questions, which I would like to direct here to the members of the panel. This is to Dr. Roper and Dr. Wilensky. The legislative history of CLIA in '88 specified very clearly that the waivers were to be based, first on the error-proofness of the test, and second, on the minimal risk to the patient of an erroneous test.

What evidence do you have that your wavered tests meet these criteria?

Mr. Roper. You are asking, sir, what criteria were used in assigning specific tests to the waiver category?

Mr. Dingell. Yes.

Mr. Roper. I do not have with me the specific evidence, but the basis for that was a series of consultations we had with our colleagues in the Food and Drug Administration and comments that we had earlier received on another proposed rule. It was a general assessment of the state of the art.

Mr. Dingell. Dr. Roper, I have here, on the letterhead, Department of Health and Human Services, Public Health Service, Centers for Disease Control, a memorandum dated January 30, 1990. That memorandum is signed by R.O. Valdesari, for Joyce E. Essian, M.D., MBA. In that the communication says as follows. Are you familiar with the document?

Mr. Roper. No, sir, I am not, but please go ahead.

Mr. Dingell. It sets forth the position of the Centers for Disease Control. This is on January the 30, 1990. It says, "the ASPE position is that any small possibility of false negative or false positive tests posing an unreasonable risk should be rejected."

They believe that because of the substantial amount of misdiagnosis in medicine, generally, that it would be more risky to provide a test for which there is significant probability of error than it would be to fail to provide the test altogether. They indicate that the risk to the patient of erroneous testing can be reduced by the context in which the test is performed, namely, the clinical questions and follow-up procedures. They believe that the limited number of waiver tests currently listed might influence physician laboratories to fail to provide these tests, so as to avoid Federal regulation.

They then go on to say as follows: "ASPE recommends the following: Remove option one. Option one, parenthetically, is the CDC/FDA recommendation that no waiver tests be identified until the process is established for establishing their conformity to the standards established by the Act from NPRM.

"Expand the list of tests qualifying the laboratory for certificate or waiver to include those home use tests and most of the tests currently included in the Level I list."

Now, that is a recommendation which seems to be at variance with what was finally done. Am I correct or incorrect?

Mr. Roper. If I follow that, sir, and again, I have not read that letter, that is at variance with what was finally done, yes.

Mr. Dingell. So, CDC's original position was that there should be no waivers, essentially?

Mr. Roper. If you will excuse me just a moment?

Thank you, sir, for your patience. I am informed that the original position was that studies needed to be done before the classification was put in place.

Mr. DINGELL. I agree with that statement. Were those studies done?

Mr. ROPER. No, sir, because of the urgency to press ahead with this regulatory effort.

Mr. DINGELL. Well, your original position was that studies should be done and that those studies should identify areas where you could properly have tests on a waiver list.

Mr. ROPER. The other factor that went into the decision that the CDC made was the comments that were made to the proposed regulation published in August of 1988, affecting clinical laboratories, and those comments led to the decision that CDC ultimately took.

Mr. DINGELL. Was there evidence in those comments that there was no risk?

Mr. ROPER. I would just have to go back and review them, sir.

Mr. DINGELL. I am trying to understand. On January 30, 1990, it was the position of CDC that there should be no waivers until there had been a process established for establishing conformity to the standards established by the Act. Something happened, then, which caused CDC to change its position.

Mr. ROPER. What happened was a judgment that we reached that the comment period on this regulation that we are here discussing would be a more productive comment period if we put forward in the proposed regulation examples of what we believed at that time to be appropriately waivered tests.

Mr. DINGELL. In other words, you are telling me that that judgment caused you to substantively change your positions?

Mr. ROPER. Well, you're asking my position, and I do not want to separate myself from the Agency's position——

Mr. DINGELL. I am asking CDC's position.

Dr. ROPER.—because I agree with it; I was not there at the time.

Mr. DINGELL. You are testifying on behalf of that agency.

Mr. ROPER. Pardon me, sir?

Mr. DINGELL. I am asking CDC's position. You are testifying on behalf of that agency.

Mr. ROPER. I am, indeed.

Mr. DINGELL. OK. Now, Saint Paul was struck by a bolt of lightning while on the way to Damascus. It knocked him off his jackass, blinded him, and he suffered a tremendous revision of his position with regard to Christianity.

What lightning bolt or what else was it that hit CDC to cause them to change their position?

Mr. ROPER. A reflection on how we could most productively undertake this rulemaking process, plus the additional comments we received over the months just prior to the regulation going forward.

Mr. DINGELL. What were those comments, and where did they come from? Am I to assume that they are from OMB?

Mr. ROPER. No, sir.

Mr. DINGELL. They were not?

Mr. ROPER. No, sir.

Mr. DINGELL. Were they from Dr. Wilensky?

Mr. ROPER. They are public comments. I would be glad to supply them to you.

Mr. DINGELL. Who was it that made the comments, and what were the comments?

Mr. ROPER. If you will recall, sir, HCFA published a regulation affecting clinical laboratories in August of 1988. There was a large number of comments on it, and some of them touched on this same issue.

Mr. DINGELL. Well, let us just go through some of these.

Mr. ROPER. The further thing that we were guided by is the structure of the law that the Congress passed, CLIA 1988.

Mr. DINGELL. A curious thing. I was there when we passed the law. I had a little bit to do about it. Matter of fact, I even wrote a modest amount of the legislative history. I did so in consultation with people like Mr. Wyden, who were the other authors of the statute.

In that I said that the provision directs the Secretary to determine those simple examinations and procedures that have an insignificant risk of an erroneous result with the purpose of establishing a test appropriately qualifying a laboratory for a potential certificate of waiver. It is the intent of the Congress in employing this language that the Secretary bases all determinations about whether individual tests have an insufficient risk of an erroneous result on both probability and/or an erroneous result and clinical relevance of an erroneous result. Specifically, a finding of insignificance would first be based on a determination that a test was inherently so simple that the probability of obtaining an accurate result irrespectively of how the test was performed would be so small as to be without meaning. Next, the Secretary would need to consider the clinical relevance by determining the effect of an inaccurate result on a particular examination or procedure would have no consequences for a patient.

Now, that's the history.

Mr. ROPER. Yes, sir.

Mr. DINGELL. Do you disagree with it?

Mr. ROPER. No, sir; not at all.

Mr. DINGELL. OK. Do you disagree with it, Mr. MacRae.

Mr. MACRAE. No, sir.

Mr. DINGELL. Do you disagree, Dr. Wilensky?

Ms. WILENSKY. No.

Mr. DINGELL. Very good. We have established the basis. The Chair is now going to recognize those members for questions, because my time has run out, and we will come back to this interesting issue in a bit.

The gentleman from Oregon, Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

A question for you to begin with, if I could, Mr. MacRae. It is the position of OMB, as I read the testimony, that what is being proposed essentially will increase costs and reduce access.

Could you briefly outline the studies that you have accumulated or done that would justify the OMB position that what is being proposed would increase costs and reduce access?

Mr. MACRAE. It is not so much the question of studies, but the question, it seems, that the appropriate discussion of the proposal, proposed rule that would invite public comment as to could there be any perverse or unintended effects from the enactment of what the chairman just described, and that is our role, I think appropriately, just to make sure that those questions are raised. It was not in regard to a specific study or something like that. It is clear that this rule is going to be a fairly expensive rule, I do not think there is any doubt about that. It is obviously intended to have a beneficial effect on the health status of the population. Therefore, the tradeoff, as I mentioned in my testimony, in some cases may be that if the costs were to be too high, such that labs would have to close or people would have to travel further, too far to be tested, that could have the same effect, that is, if one is not tested, as a false negative.

Mr. WYDEN. At this point, OMB has no information and has done no studies on this question of costs going up, or of access. What I see you doing is in effect just speculating about the possibility of dire increases in cost and massive closures. What I would like to know is whether you have any concrete proof. Unless you answer my question differently, what I am gong to do is just take away the notion that as of now OMB has proof.

Mr. MACRAE. One of the things that is interesting, as the Congress itself recognized, and has required so-called section 4 studies in public health enactment, and it asks that five areas be studied.

The problem we face is, we do not know. We just do not know; but it is not improper to speculate as to what the effect may be. The thing that needs to be done is to in fact get these studies done, get the information gathered, that would allow people to make a judgment. All we were trying to do is make sure that the questions were raised in such a fashion that people could, the public, in commenting, could respond on those points.

Mr. WYDEN. It is going to be 4 or 5 years until the studies are done. The fact is, Mr. MacRae, the Congress of the United States, on a bipartisan basis, made a judgment. That is why we enacted the Clinical Laboratory Improvements Act Amendments. You all are making judgments to hold things up——

Mr. MACRAE. No, sir.

Mr. WYDEN. Further delay without any information on costs and without any information about the impact on access.

Mr. MACRAE. We did not hold up these rules at all.

Mr. WYDEN. Why do you not just give us any information that you have about the impact on cost or the impact on access. Once again, do you have any studies that you can point to now?

Mr. MACRAE. We do not have specific studies, no, sir.

Mr. WYDEN. Thank you.

Dr. Wilensky, a couple of questions for you.

On this process of involving the experts, and trying to get their opinion to expedite these technical considerations, HCFA does not conduct public hearings on rulemakings, does it?

Ms. WILENSKY. Not normally.

Mr. WYDEN. Is HCFA precluded from holding public hearings to discuss the issues in open forum so that you could try to work out differences in technical areas and reach a consensus on relevant issues?

Ms. WILENSKY. To the best of my knowledge, we are not precluded. We do hold meetings of various sorts, and we have indicated to the committee the conferences and meetings that we held with regard to this particular piece of legislation.

Mr. WYDEN. What we have been told by one group of experts after another, and I have heard from many myself, is that these were not meetings that involved interaction so that people could really give their input and work towards resolving differences. There were some sessions where people from the Department came and gave speeches, but there was not any effort to try to turn this around.

I guess my question is, at this point, would it not be helpful to get some kind of advisory committee together very quickly with the express purpose of having some interaction and trying to resolve these differences?

Ms. WILENSKY. If you are interested in getting the rule out in an expeditious manner, I do not believe it would be advisable.

The issue about whether or not meetings and conferences are equivalent to hearings is obviously somewhat open to the interpretation of the people present.

I personally, since I have been at HCFA, which was, for the most part, after the rule and the comment period, have had dozens of meetings with individuals and groups in which they have shared their comments. The fact is, there were a lot of meetings. There were at least a couple of all-day conferences; and I think there was a fair amount of information exchanged. There is no question the information we received after publication of the proposed rule was far, far greater than anything that we received before.

I believe that the process we have now in place, using the experts and the CDC and the FDA, and the incredible amount of information that we were provided with, is the best way to go ahead. I believe it will seriously delay final publication if we have such an advisory committee.

Mr. WYDEN. I just want to point out that what the experts are telling is that there have not been meaningful meetings with the experts and the parties in the field; that, in fact, there have been no public hearings; and the fact that there has not been an advisory committee or something similar to that that would assist the Department on an on-going basis has further delayed things.

I just want to ask one more question, because I know my light is on, if I can have the Chair's indulgence.

My sense of what this is really all about is that the Department has never felt that there is a real problem with inaccurate medical tests.

Ms. WILENSKY. That is absolutely——

Mr. WYDEN. Let me just finish my question. I went back through the record and I tried to find instances where the Department did say that there were serious problems with inaccurate medical tests, and really, to their credit, people in the Department have been very consistent. This is not something that they did just once. It was all through the record.

What I would like to do as my last question for this round is to have you or Dr. Roper spell out for us now what you think the problems are with inaccurate medical tests.

Specifically what problems do you think there are out there and how serious are they?

Dr. Wilensky?

Ms. Wilensky. The issue that we have not taken the implementation of this legislation seriously——

Mr. Wyden. That is not the question. The question is, because——

Ms. Wilensky. That was your first point.

Mr. Wyden. I formulated a judgment that I do not think the Department thinks that these are serious. I would like to give you and Dr. Roper a chance to respond, and for you to tell us whether you think these problems are serious, and in what areas they are, so that we can get your view.

Ms. Wilensky. I think that I, personally, based on what I have read, am not in a position to know this. We are not in a position to know this because there are no national standards; there are no national regulations; and there are inconsistent State regulations. Therefore, that certainly raises the possibility of problems in a variety of areas.

I have read some of the hearings that led up to the legislation that resulted in CLIA, and there certainly is an indication, on an anecdotal basis, of some terrible problems.

I do not believe we have a way of judging the seriousness of the extent or the frequency with which this happens. I regard this legislation as an attempt to try to make sure that there is sufficient oversight in regulation so that problems of this nature are minimized. I do not believe we know the extent of these problems. I take it that the will of the Congress has been made very clear about this legislation, and I regard that very seriously.

Mr. Wyden. Mr. Chairman, I just feel that this is the central problem. We have documented what the problems are. The College of American Pathologists, which accredits the best hospital labs, said one out of ten tests that involves platelets, which are designed to detect leukemia, are not read at an accurate level. We have documented the problems, and yet those of you at the witness table have said, and I know you are very sincere, that we do not know yet what the extent is and that it is just kind of anecdotal. Mr. Chairman, I think that is the heart of the problem.

Mr. Roper. Mr. Chairman, could I respond to that as well?

Mr. Dingell. Dr. Roper, you may respond.

Mr. Roper. Thank you.

I just would like to say, as directly as I can, that I categorically reject Mr. Wyden's suggestion that this Department or that we as individuals do not take this issue seriously.

He said that he read last night the transcript of the hearings that you all held back in 1988. I did that as well, yesterday. I was here, as you both know, and I would be willing to cite you many references in the text of the hearings of March 10 and of July 6 of that year when I gave you my personal estimation of the problem, and the fact that what we were trying to do in the Spring and Summer of 1988 was to pass comprehensive regulations improving the quality of laboratory services in America, at the very time you were deliberating this legislation that ultimately passed. The legislation came along. Surely it was well-intended, but that added a whole set of complexity to this issue that has delayed the process.

I categorically reject the suggestion that any of us has delayed this out of some sense of inattention to the Nation's problems.

Mr. WYDEN. If the Chair would indulge me, I again asked Dr. Wilensky, and I ask you, to tell us what you think the problems are today with medical labs, and how serious they are.

Mr. ROPER. I think it is a serious problem.

Mr. WYDEN. What are they? Are they problems with Pap smears; are there problems with platelet counts? I would like to know, so we could go forward today with some sense of whether Federal agencies feel that there are problems in specific areas like Pap smears, or some other area. I would find that very enlightening.

Mr. ROPER. The answers you seek are the same answers we seek, an estimation of the range and depth of the problems. That is what we are going to find when we undertake these studies that we have underway.

Mr. DINGELL. The time of the gentleman has expired.

The Chair is going to recognize the gentleman from Virginia, Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. MacRae, you testified that the OMB review of these rules was completed in an average time of 41 days, I believe.

Mr. MACRAE. Yes, sir.

Mr. BLILEY. Were these calendar days or working days?

Mr. MACRAE. Those are calendar days, sir.

Mr. BLILEY. What is the usual review time in other cases?

Mr. MACRAE. Depending on the complexity of the rule—we have major rules and then we have minor rules—the review time can vary between an average, say, of 15 days and can range up to 50 or 60 days.

We have considerably reduced the review time, average review time, from what it used to be. We have also virtually eliminated rules that are under review at OMB beyond 90 days.

Mr. BLILEY. So 41 days for—I assume you consider this a major rule—is not an inordinate amount of time?

Mr. MACRAE. That's true.

Mr. BLILEY. Historically.

Mr. MACRAE. Yes, in fact the major one of those rules, the principal rule of the four rules, was actually done in 22 days.

Mr. BLILEY. OMB waived the regulatory impact analysis, the RIA requirement, for all of the implementing rules because implementation of CLIA was behind schedule, isn't that correct?

Mr. MACRAE. Yes, sir.

Mr. BLILEY. How much additional time would have been spent had you not waived RIA? Can you give us an estimate?

Mr. MACRAE. I really wouldn't like to say how long it would take.

Ms. WILENSKY. It wasn't the review. It was that the work that would have been involved in terms of attempting to do the impact analysis would probably have been a couple of months, based on our assessment of the impact analysis we will ultimately be doing.

Mr. Bliley. Thank you, doctor. Mr. MacRae, the Office of Information and Regulatory Affairs filed a public comment on the proposed rules.

Is this unusual?

Mr. MacRae. Not in the case of major rules where it's important to get the rule out. If there is a statutory or judicial deadline, we do file public comments so that our review will not be taken in any way as a delay of getting the rule out.

Mr. Bliley. Dr. Wilensky, your agency has proposed a provisional certification fee that will be assessed on all physicians and laboratories covered under CLIA '88. This type of fee is allowed, in fact I believe it is required, under CLIA, is this not correct?

Ms. Wilensky. That's correct.

Mr. Bliley. How much is the fee?

Ms. Wilensky. $261.

Mr. Bliley. How did you arrive at $261?

Ms. Wilensky. Probably a false sense of precision with the $261. The purpose of the fee is that the whole set of regulations are to be user fee financed and therefore what we have done is to estimate the cost associated with various activities.

The $261 covers the preliminary activities that had to be undertaken in order to get to the point of implementing the clinical lab regulations. It was our estimate that that was the revenue that would be required, some $80 million, in order to carry out the first stages and get to the point of actually conducting surveys after the more detailed regulations are published.

Mr. Bliley. How many comments did you have on the proposed regulation?

Ms. Wilensky. Not very many; 93.

Mr. Bliley. The proposed rule on laboratory standards generated many more comments than that, did it not?

Ms. Wilensky. Yes, sir, 60,000.

Mr. Bliley. Why do you believe so few comments were received on the regulatory concerning the fee?

Ms. Wilensky. Well, I assume that the basic assessment that was being used in an attempt to set up a fee structure was regarded as appropriate. It was not only this provisional certificate that was included but it was the subsequent charges that looked at the level of testing, the number of tests and the complexity of the tests performed in a lab. Those were used to set up a little matrix to determine what a lab would be charged.

I would assume that the basic strategy that underlay the fee structure was regarded as appropriate.

Mr. Bliley. Have any standards been developed to support the provisional certificate?

Ms. Wilensky. Well, the provisional certificate is basically a registration and a request for information.

Mr. Bliley. What does the fee pay for?

Ms. Wilensky. The fee will pay for the activities associated with collecting information and the beginning parts of implementing the law.

We have, as we have been discussing——

Mr. Bliley. The rulemaking.

Ms. Wilensky. The rulemaking, yes.

Mr. Bliley. What costs have been incurred to date in promulgating the rule? Can you share that with us?

Ms. Wilensky. An enormous amount of time has been devoted to this rulemaking activity in the CDC. Dr. Roper has alluded to the enormous amount of time CDC has spent. The Health Care Financing Administration currently has some 52 people involved in this activity.

The series of studies that have now been put out at least for their design, there's just been an enormous amount of activity in the department to get to the stage we are now at.

Mr. Dingell. Will the gentleman yield?

Mr. Bliley. I'll be happy to yield, Mr. Chairman.

Mr. Dingell. It's a very interesting question.

Now, I am curious about this provisional certificate and what it costs and what it does and whether it's authorized in the statutes, so let's go through it. First of all, this provisional certificate is not authorized in the statute, is it?

Ms. Wilensky. I don't know—I'm not sure. I will tell you an answer. I'm not sure I'm answering your question but it is my understanding that the statute as it is written indicates that all activities associated with this——

Mr. Dingell. But the statute does not authorize the issuance of provisional certificates. Nowhere—I have read the statute having been directly involved in its enactment and nowhere in it that I am aware of is there language authorizing the creation of or the sale of provisional certificates.

Having said that, what does the provisional certificate do, other than allowing the holder thereof when he gets it to pay $260 to the Federal Government?

Ms. Wilensky. It will serve as a——

Mr. Dingell. Pardon? It will serve as a——

Ms. Wilensky. It will be the only information that we have until we do an actual survey and certification.

Mr. Dingell. So you are using this as a surveying device. They are paying $260 to be listed in a survey, is that what you are doing?

Ms. Wilensky. It is to provide an official registry as to who will be involved in this program because this is an initial entrance into the program. Up till now we do not have an official listing of who is currently providing laboratory services in this country and the information about the number and types of tests and the number and types of personnel that work in these laboratories. This will establish the initial registry of all laboratories that will subsequently either continue or not continue in the program.

Mr. Dingell. I thank the gentleman for yielding. I will not take that out of his time.

Mr. Bliley. Thank you, Mr. Chairman.

Getting back to my previous question.

Ms. Wilensky. Yes.

Mr. Bliley. You have performed as you said an awful lot of work. Since CLIA mandates that the programs that you described be paid for through user fees, have the costs been met?

Ms. Wilensky. Well, up until now the department has been basically providing all of the funding. We have not yet collected any user fees and we have been working on this activity since the beginning of 1989, so in fact we have spent an enormous amount of money that was not appropriated for labs. We have had to put the money up front.

Mr. BLILEY. When will the provisional certificates no longer be provisional?

Ms. WILENSKY. As soon as the actual certification occurs, according to the level and number of tests that are performed. This will begin as soon as the final rule is actually implemented and in force.

Mr. BLILEY. When do you expect the final rule to be in place?

Ms. WILENSKY. Well, we expect the final rule to be published at the end of the calendar year, either the end of December or the beginning of January. There is a 120 day delay prior to implementation. It is our expectation it will be operational in May of 1992.

Mr. BLILEY. All right, and now long after that, after May, 1992, will the certification process take, in your estimate?

Ms. WILENSKY. It will be done by——

Mr. BLILEY. Right away, but I mean how long?

Ms. WILENSKY. Well, normally our survey and certification process occurs all throughout a year. So the answer is once it starts it will be ongoing thereafter. This is something that occurs on an ongoing basis and laboratories get brought in, as opposed to occurring at a single point in time.

Mr. BLILEY. How often do they get checked?

Ms. WILENSKY. Once every 2 years.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. DINGELL. Dr. Wilensky, just one more item on the record before we recognize other members.

You have not yet met a single one of the deadlines that have been fixed in the statute.

Ms. WILENSKY. That is correct.

Mr. DINGELL. Not a one?

Ms. WILENSKY. Not a one.

Mr. DINGELL. Mr. MacRae, perhaps you could help us. Is this true that the holdup's at OMB?

Mr. MACRAE. No, sir.

Mr. DINGELL. It's not? Why, Dr. Wilensky, have you not met the deadlines?

Ms. WILENSKY. The most fundamental reason is that the work and the time that was required in order to come to some consensus and put out a basic rule in May of 1990 took far longer than we had envisioned.

Some reasons for that are the lack of consensus in the scientific community as to the riskiness involved in tests, the complexity involved, and the type of personnel that is appropriate.

There were a large series of meetings. Although I was not present during that time, I have been briefed on the enormous difference of opinion that has existed, not only in the Department but, also with outside groups. The advice that we were provided put us in a position of trying to reconcile these differences.

The decision was made ultimately, I believe correctly, that we simply had to take the information that we had, put together a proposed rule to the best of our capability, put it out for the public comment period, and have the public process that proceeds after that.

We had an extraordinarily long comment period. We normally have a 60 day comment period. We had a 90-day period, 50 percent longer. We had an enormous flood of requests the last 10 days of the 90 days, including 270 letters from Congress, for additional time because of the complexity of the statute. We extended the comment period to a fourth month and then we received, somewhat to our surprise, this enormous outpouring of information as Dr. Roper indicated, sometimes hundreds of pages of data as well as comments were received. We are now responding to the very helpful information that has come as a result of the publication of this proposed rule. We are proceeding as quickly as we are able to.

Mr. DINGELL. Thank you. The gentleman from Kansas.

Mr. SLATTERY. Thank you very much, but the gentleman from Georgia has the time.

Mr. DINGELL. The gentleman from Georgia is yielding.

Mr. SLATTERY. And I really do appreciate that very much. I just had a few questions of Dr. Wilensky regarding the whole issue of how these regulations impact rural America, and I first want to acknowledge that you have been very responsive to our rural health care caucus, and I appreciate the time that you have spent with us in trying to make sense out of what we're doing in this area.

I had also observed that this whole discussion is sort of a microcosm of the broader health care issue in the country. Everybody wants immediate access, preferably on their block someplace. They want it cheap, and they want the Rolls Royce quality, and they want it all now.

Ms. WILENSKY. That sums it up pretty well.

Mr. SLATTERY. And I realize this is a very difficult task that you're undertaking, and out in rural America, it's even more seriously complicated by the fact that we have a serious shortage of certified technicians and technologists that are needed to operate some of this equipment that is involved.

To the extent that we demand that those people be on the site, we compromise access, and when you compromise access, you compromise care, and when you compromise care, you obviously compromise the quality of care and you compromise the whole health care delivery system out there. So there has to be some acknowledgement of this and some compromises made to acknowledge this.

I wanted to specifically focus on this question of how you all have arrived at this distinction between Level 1 and Level 2, and how you have sort of fit some of this machinery into these rather arbitrary designations.

I have heard from some physicians that indicate to me that on the May 21 rule, you would allow them in effect to continue to perform about five of the 27 different kinds of tests that a certain machine is capable of performing, and the same methodology is used for all of the tests. Yet, we're sort of arbitrarily said under this proposed rule, apparently, that you can only do five of these under Level 1.

If the physician out in the rural community wants to continue to perform the other 22 that that machine is capable of performing, then he would have to hire a PhD laboratory scientist or a pathologist as a director, and a license medical technology with requisite education and training.

This is one of these kinds of problems that we get into that, on its face, doesn't seem to make a lot of sense.

Again, I thank you for your willingness to respond to some of our unique concerns, and I'd just like to have your input on how you deal with something like this. In the final rule, are you going to make an adjustment to perhaps make this make a little more sense?

Ms. WILENSKY. Well, let me share with you how we could have gotten to that position, since, on the face of it, it does not seem reasonable. Let me also share with you what we think we may be able to do as we work toward a final regulation.

Because the statute required us to look at both the complexity of the test itself and the riskiness to the patient if done incorrectly, we could have tests where the risk of being wrong differs even though the complexity of the nature of the test itself might be comparable.

It's why you may have different levels among tests that are done with the same technology if the risk of having it done incorrectly or interpreted incorrectly is different. So that's sort of the general response as to why something that a single instrument will do could, in fact, end up in different categories.

We were toying with this issue of how to try to distinguish the various levels that a test ought appropriately to go to, and I think some of what I have heard expressed today by the members and by other witnesses indicates the kind of struggle that we have had. That is, there is a group of people who believe there is no such thing as a risk-free test, and we certainly heard that in parts of the scientific community.

On the other hand, you hear terms like "insufficient risk" or "probabilities." You begin to take absolute terms and have some probability associated with them. That begins to require some sort of judgment and balance, and the difficulty of defining that becomes very much more difficult, both the test itself and the riskiness of what happens to the patient if it is done wrong.

Mr. SLATTERY. If I might interject, I'm advised that in many of these machines, I mean the methodology is so simple that the error rate is extremely low that it's just almost impossible, and that the problem might come in in the interpretation of the results. But in terms of just input and looking at output, there is very little chance for error. It's just like running a copying machine almost.

Ms. WILENSKY. One of the areas that has received a lot of attention is that the proposed rule does not adequately address the issue of instrumentation and changing technology, and how that might impact on the requirements for personnel.

But I will tell you, we have actually had comments on both sides. We've had a lot of comments that we didn't adequately address the increasing sophistication of the instrument and the reduction in personnel that that might therefore lend itself to.

We have had people who specifically commented, "Watch out for the so-called goof-proof instruments that anybody can operate." That, in fact, does require some skilled laboratory people in terms of using them.

I do believe that we can look at and deal with the technology issue in a better way. We can also look at personnel requirements in view of equivalence, which we did not tend to do very much in our proposed rule. This will allow us to make sure that we do not do the kind of damage that might have occurred to rural health from the proposed rule.

We won't know a lot of this until the complexity model is completed, which we anticipate around mid-July or so, because the complexity model is integrally linked with the appropriate personnel requirements.

But we do believe that there is more room than we had accounted for initially in terms of looking at the impact of increasingly sophisticated instruments on personnel requirements and equivalence. We believe in particular, that will address some problems that we heard from the rural health community.

Mr. SLATTERY. Do you anticipate that there will be a proficiency exam included in the final rules?

Ms. WILENSKY. I don't think we have yet made a decision about that. It has been raised as a possibility. We are concerned about that. We would rather have equivalences, but we have not ruled it out, either.

Mr. SLATTERY. Thank you, and I thank my friend again for allowing me to go ahead of him here. Thank you.

Mr. DINGELL. The time of the gentleman has expired. The gentleman from Georgia, Dr. Rowland.

Mr. ROWLAND. Thank you, Mr. Chairman.

Dr. Roper, welcome back to Washington.

Mr. ROPER. Thank you, sir.

Mr. ROWLAND. It's good to see you here.

Dr. Wilensky, let me ask you—certainly, you said that you received an unprecedented response to proposed rules that you had on May the 21st. What is the current staffing level that you have now? Is it adequate to move forward, do you think?

Ms. WILENSKY. The answer, I believe, is yes. We have some 52 individuals at the Health Care Financing Administration who are about 25 full-time equivalents. They are people who have technical backgrounds, computer backgrounds, finance, rulemaking backgrounds. Working with the even greater number of full-time equivalents at CDC, which is actively involved, as Dr. Roper indicated, on the complexity model and cytology and proficiency testing.

So I believe between the two groups, we have an enormous full-time staff. I think it's something around the neighborhood of 65 or so full-time equivalents; again, a group that's probably in the neighborhood of 100 to 150 individuals working on this activity.

Mr. ROWLAND. Do you plan to proceed with developing the regulations based on waivers, Levels 1 and 2, or do you propose any alternative regulatory frame work different from—since you had so many adverse comments?

Ms. WILENSKY. Well, one of the areas that has been raised is that the number of levels might not be the appropriate. Certainly, this issue, among many others, is being dealt with in terms of the revision to the complexity model.

The issue about whether there are alternative approaches altogether to the complexity model has also been raised. This may be something that Dr. Roper wishes to address, but we are both looking at the number of levels, the match between the levels and the personnel that are associated with the levels, and alternatives to the complexity model as it now exists.

Mr. ROWLAND. Maybe Dr. Roper would like to respond, also.

Mr. ROPER. Dr. Wilensky summarized the key alternatives. We are weighing those right now and hope by mid-summer to have consensus within the department. But I'll just rehearse them for you.

One of the alternatives that is before us is the possibility of phasing in proficiency testing across laboratories so that it's not done at the beginning in all of them. A second is providing one or more additional levels in the complexity model to make it even, frankly, more complex. A third is to consider the context, perhaps including the site of the test is a judgment about its complexity. A fourth is to look at these issues of methodology and instrumentation in placing tests in various complexity levels. Fifthly, an alternative proposed by many physicians is to consider the qualifications of various types of physicians as supervisors of laboratories.

Surely, there are other alternatives, and we will be working on those in the coming 2 months.

Mr. DINGELL. If the gentleman would yield.

Mr. ROWLAND. I yield.

Mr. DINGELL. What we have, after 2½ years of the Congress sitting around waiting for you folks to tell us what you've done, is one regulation in place, which is that this—we have a provisional certification which entitles these people to pay the Federal Government $260 and hang a certificate on the wall. But that certification doesn't show that these people are competent to do anything; all it shows is they paid the Federal Government $260.

Now, is there anything I have said that's incorrect, is there actually more that you have done.

Ms. WILENSKY. That's actually not in place yet.

Mr. DINGELL. Pardon?

Ms. WILENSKY. That's actually not in place yet. The final rule won't come out until——

Mr. DINGELL. So you haven't even gotten to the point where you're going to be able to give them the certificate for $260 that shows that they've paid $260, so they're not necessarily particularly incompetent.

Ms. WILENSKY. We do, of course, have the earlier rule that came out in March. A question was asked with regard to pap smears earlier. There are, in terms of cytology, the revised so-called CLIA 67 regulations that came out in March of 1990. But you are otherwise accurate.

Mr. DINGELL. But no doctor's office is covered in that?

Ms. WILENSKY. No doctors' offices.

Mr. DINGELL. As a matter of fact, if my information is correct, you don't even know what doctors are functioning under Medicare and Medicaid, do you?

Ms. WILENSKY. No. One of the reasons that this provisional certificate is very important is that we must have this information. We need to get——

Mr. DINGELL. As a matter of fact, you had to go to other sources to find out what doctors were covered under Medicare and Medicaid. Isn't that right?

Ms. WILENSKY. In terms of the lab tests.

Mr. DINGELL. Yes.

Ms. WILENSKY. We know what doctors are providing Medicaid and Medicare services.

Mr. DINGELL. I thank the gentleman for yielding to me.

Mr. ROWLAND. Well, let me ask you, as the chairman pointed out, 2½ years, and still not in place. What were the stumbling blocks? Can you tell me what were the stumbling blocks that came in front of you to prevent you from getting these regulations in place.

Ms. WILENSKY. The single most significant stumbling block, in my opinion, is the lack of scientific agreement about the fundamental premise on which this statute rests, which has to do with how to classify by riskiness and complexity. Not that these aren't legitimate issues, but the fact is there was substantial disagreement about how to do this classification, what it meant to be either zero or very little, or more significant, or some likelihood of harm, and then the mapping of the personnel requirements that were appropriate, and the kinds of proficiency testing that is appropriate to match the personnel and the testing.

But the most fundamental difficulty, as I understand it, is the very great difference of opinion that has to do with the fundamental issues of riskiness and complexity. We have heard very different points of view about whether we have waived entirely too few, or, as may have been suggested, many more than is appropriate.

It was our presumption early on that the Level 2 that we had would primarily be independent laboratories, and therefore the kinds of personnel that were required would normally be associated or ought to be associated with these independent laboratories.

In fact, what we have had information come back to us is that because of the advanced instrumentation, many of the tests that are in our Level 2 are provided routinely in physician office visits, and we can regard that as either good or bad. It was information that I think we learned as a result of this. But I think the fundamental problem is the difference of view in the scientific community.

Mr. ROPER. I think that's something I'd echo. The law says clearly, we want tests to be accurate, we don't want anybody to be harmed, and we want that to be true across the country, regardless of the site in which those tests are done. Very worthy goals, but it's extremely complex technically and scientifically, and it's taken us a while to get there.

Mr. ROWLAND. Because of the complexity of the issue, the diversity of opinion that you had, do you have any concern that once you move forward with this, that you are going to again encounter all of the outcry that you encountered before?

I was listening earlier, Dr. Wilensky, and a question was asked about whether or not you thought a hearing and talking with people—and you've had some meetings, you said. I really wonder if it wouldn't be better to talk some more with the people or have a hearing, in spite of the time constraints that you feel that you are under, to try to put in place something that is not going to create problems because of the complexity of this issue.

Ms. WILENSKY. Well, let me share with you why—although, you know, I don't want to say that you don't lose something every time you engage in that. I don't really believe it's required, and I think there's at least one other way that we have sometimes used that we could respond, I think, to the concern that you've raised.

We in the Health Care Financing Administration, and, I assume, probably also CDC, have had many, many meetings with various groups during the comment period. I have met with the College of Pathologists and the head of the pathology group six, eight, ten times, just myself. Many of the groups that requested to have meetings came in and spoke to us in the administrator's office and to the technical and scientific people as well.

With 60,000 comments and some sense about the information behind them, you do begin to get to the point where it's hard to believe there's anything out there you haven't heard. You read who it is saying what and what is their reason for saying that, and how often it comes up.

So I think that, between the various meetings that we've had, the written comments that we had, which are, of course, necessary to be on the record, that we really do have a good sense about how people think about things.

When we put out the CLIA 67 in March, we put out a final rule with a 60-day comment period. Although we can always redo a regulation, a final with comment is a mechanism that we sometimes use if we want to have an easier way to do a revision, should that be necessary. We have not made a final decision as to whether or not that is appropriate.

It is certainly something, as we get to the point of publishing the rule, that we will raise, as I indicated. It is something that we used in March of 1990 because we thought there might be still additional comments after we had taken advantage of all the comments that we had heard.

It is, in my opinion, something that, at this stage, I don't believe would be particularly advantageous. Now, again, I don't want to say that we wouldn't learn anything at all, but I really do feel like we have had an outpouring of information, enormously helpful in our deliberations.

I really regret that we didn't have a fraction of this prior to the time we put out our proposed rule. I believe we were trying to have that occur. Obviously, some groups either didn't believe it, or they didn't take advantage of it, or they didn't know what we were up to, or whatever. But there's nothing like a proposed rule to prompt responses that haven't been forthcoming before that.

Mr. ROWLAND. I see that my time has expired. Thank you.

Mr. DINGELL. The gentleman from Oregon.

Mr. WYDEN. Thank you, Mr. Chairman.

A couple of other questions for you, Mr. MacRae. Your concerns regarding the definition of a laboratory also single out mobile lab public screening for cholesterol as a concern. Now, there's been a great deal of evidence that some of the testings in these public screenings simply aren't reliable. Is it OMB's position that these mobile public screenings should not be regulated?

Mr. MacRae. No, sir.

Mr. Wyden. Then OMB would support regulation in the area of public screenings for such things as cholesterol?

Mr. MacRae. We would support—I am not a doctor, and so, therefore, I would not wish to venture into this area. But to the extent that the Department thought it was appropriate to regulate those areas, we would certainly concur with that.

Mr. Wyden. But I want to make sure we understand OMB's position. We have this document. My Subcommittee on Regulation looked into this area. Mr. Kusserow helped us and went at great length through the problem as it relates to cholesterol testing at some of these public screenings. So it's documented. Are you saying at this point that you're willing to go along with the recommendations of someone like Mr. Kusserow?

Mr. MacRae. I'm willing to go along with the recommendations of the Secretary of Health and Human Services. I do not know whether Mr. Kusserow has discussed this particular point with the Secretary, but obviously, the question of rulemaking with regard to these particular facilities is a decision to be made by the Department, not a decision to be made by OMB.

Mr. Wyden. OK. Dr. Wilensky, one other question for you, if I could. CLIA allows for incremental implementation of the various elements of the Act, and it seems to me that even if certain of the deadlines couldn't have been met, the intent of the statute could have been followed by going forward with registration, plans for inspection, the intermediate sanctions, conditions for action on certificates. All of these steps are specifically proscribed by the Act.

Why has the Department chosen not to go forward with any kind of incremental implementation of the various elements of the Act, specifically because Congress made provision for this kind of approach. It would have given a chance to get some protection to the public wouldn't it?

Ms. Wilensky. Well, the issue is kind of incrementalism and whether it seemed to help or put us in the right direction. Let me give you an example:

We did not go forward with the registry which we are very interested in doing because we want this information about laboratories. The law required an initial licensure in January of 1991. At that point, we had the proposed rule out. We did not have the final rule out. It was the advice of our general counsel that we would place the whole activity in jeopardy if we attempted to collect fees and do the registry prior to the final rule.

As soon as we have the final rule, which we expect in May or June, we will begin that process. With regard to the enforcement, again, that is something that we have been advised that until that rule is finalized, we can't go forward. The fundamental issue has been that the complexity model drives the whole process.

Until we have really gotten that resolved and fixed the problems we obviously ran into on our proposed rule, we don't have something to implement, other than what was associated with the CLIA-

67 which was responding directly to the cytology and Pap smear concerns.

Mr. **Wyden**. Well then, are you all opposed to any kind of concept of moving forward with incremental implementation of the statute?

Ms. **Wilensky**. Not in principle. In this particular case, because the complexity model is scheduled to be completed this summer and the personnel requirements are integrally involved, unless we fall off the schedule, I don't believe it will help. I do believe it could slow things down.

Now, if something happens that we do not foresee now, that might be a perfectly reasonable strategy. Right now, given the schedule that we're on, I don't believe there's any way that incrementalism will speed it up.

Mr. **Wyden**. But you're not ruling it out?

Ms. **Wilensky**. I'm not ruling it out.

Mr. **Wyden**. I would only say that I'm very, very anxious to work with the Department on this. No one has ever said that this was an easy area. Frankly, I went along with the provision for simple tests, even though in my gut, it told me that there were going to be serious reservations.

When you tell somebody who has been injured that it was a simple test, they say, fine, glad to hear from the Government that it was simple. What I was interested in was being protected. The Congress has understood that this is a complicated statute, but I have to tell all of you—Mr. MacRae told us that he didn't have the cost analyses and the studies that were done for these various projections about access and the impact on labs in rural areas and skyrocketing costs and the like.

I thought that an incremental approach was something that could have been worked out with accrediting bodies and professional organizations and in a partnership with the States. Several of the most aggressive States have said that the Department's approach to the cytology issue was unworkable.

We've got an awful lot of work to do here, and I just hope that under Chairman Dingell's leadership, we aren't back here rehashing the very same issues in 5 years, because we have already documented the problems. We documented the problems years ago.

You said you thought they were anecdotal. Bill Roper, who is a good man, and who I have worked with on a number of issues, said that he's interested in trying to find out what the problems are. We know what the problems are. CAP and other organizations have documented them.

Now, what we've got to do is to get the solutions in place. Under Chairman Dingell's leadership, we're very anxious to work with you, but people are suffering while this just goes on and on. I thank you, Mr. Chairman.

Ms. **Wilensky**. We hope that we will be able to work with you. We are working with New York and Maryland to see whether or not, in the area of cytology and proficiency testing, in particular, they may be able to come in and, in fact, come up with testing programs. There is some problem that we're trying to resolve with them.

Mr. Dingell. The time of the gentleman has expired. Now, we have a bunch of fancy machines that you put something in and you push a button and a bunch of lights go on and off and all of a sudden, out of the other end comes a tape or a readout which tells you everything is OK or you have this percentage and that percentage. That's all that you have to do to make these machines work?

Ms. Wilensky. Well, as is almost always the case, there's a fair amount of dispute about whether the machines are absolutely infallible, or whether or not the training of the individual that's using them is also involved.

Mr. Dingell. I'm assuming that you're telling me that because you've got tests done on these machines on the waiver list, that they're infallible and we can accept their word the same way we can the Pope. Is that right, or is that wrong?

Ms. Wilensky. The tests that are on the waiver category are the tests that we were told have very minimal risk associated with them if done incorrectly and are of minimal complexity.

Mr. Dingell. You can use waiver in two instances; one, where the probability is very small; right?

Ms. Wilensky. Right.

Mr. Dingell. Two, where the risk, if there is any, is also very small; is that right?

Ms. Wilensky. That is correct.

Mr. Dingell. Now, these wonderful machines, they don't require any calibration?

Ms. Wilensky. It is the test itself that has to do that. This is not——

Mr. Dingell. You don't have to calibrate these machines? They don't have to be calibrated? You don't have to clean them? You don't have to have use reagents that have to be fresh and current? There are none of these requirements? Maybe you would want to comment on this, Dr. Roper?

These machines, I gather, are just like the Pope? You send them a little offering and he sends you back the answer which comes directly from the Almighty; is that right?

Mr. Roper. No, sir. If that's true, your understanding is different from mine.

Mr. Dingell. I'm sorry?

Mr. Roper. You were asking if that's the case? No, that's not the case.

Mr. Dingell. You've got to have reagents; you've got to see that the reagents are up to date. You've got to see that the operator knows which button to push, that he or she is reasonably literate. You've got to see to it that the machine is calibrated; don't you?

Mr. Roper. Sure.

Mr. Dingell. I assume that you believe then that there's no risk in using these wondrous machines; that you can pick up any blockhead off the street and he can run in and run this machine and that there's no risk to the fellow whose urine sample or blood analysis he's going to run. Am I right or wrong?

Mr. Roper. Well, Mr. Chairman, I don't understand your underlying point.

Mr. Dingell. I'm trying to understand how these wondrous machines are going to guarantee me an infallible result.

Mr. Roper. They're not. The waivered tests are not those in the complex machines that you're describing.

Mr. Dingell. They're not?

Ms. Wilensky. They're mostly dipstick.

Mr. Dingell. I was under the view that these waivers were going to be given to machines which were going to do all these wonderful things and that you could take any shorthaired jackass in off the street and he could run this machine and get you a great answer. Am I in error?

Ms. Wilensky. I don't believe that's correct. My understanding, in terms of what is currently on the waiver level—and there's a specific number, some 20 or 22 tests and also an even smaller number of about 15 tests in Level I, that these are not the great numbers that we are talking about in terms of instrumentation. In fact, many of the comments that we received had to do with the fact that we were not properly taking into account what instrumentation could do, and that we had improperly classified as Level II tests, tests that really weren't as complex because of the instrumentation and what that allowed.

Now, we are trying to deal with this issue now, but as you probably know, as not either a physician or a scientist—I'm an economist—I'm looking at this waiver test. They don't look to me, as I understand them, these dipstick and some of the other tests, that they are using fancy machines that you pump something in and something comes out.

Now, that doesn't mean that something can't go wrong with them, but they were the best attempt we could make at classifying tests that had a very low level of complexity and a very low probability of a problem occurring.

Mr. Dingell. Let's look at this. This is interesting. Now, you've mentioned that on the list you've got glucose in the urine. That's a wondrous machine that gives you a perfectly adequate printout in all occasions and there's no way some blockhead can screw up the test.

Mr. Roper. It's really not a machine, sir.

Mr. Dingell. Beg your pardon?

Mr. Roper. It's really not a machine. It's a piece of plastic that has a material that turns different colors, depending on how much sugar is in the urine.

Mr. Dingell. All right. OK, now we understand it's not a machine, but it's a piece of plastic that gives you a color change. Would I be unfair in assuming that if a fellow was to have this glucose test performed and he's trying to find out whether he had diabetes or some condition like that——

Mr. Roper. No, sir, that's not used to make the diagnosis of diabetes, but rather to manage a patient who is on insulin to determine, usually on a daily basis, whether the amount of insulin——

Mr. Dingell. To see if he's getting enough or too much insulin and if he's liable to go into diabetic shock. So, you're not going to be worried—diabetic shock is not an event of catastrophic character for some fellow who is going to get it; is that it? We should just be comfortable that any knothead putting a piece of plastic in a urine sample is going to be able to provide this fellow with adequate assurances that everything is fine; is that right?

Mr. ROPER. No, sir.

Mr. DINGELL. That's why we've got——

Mr. ROPER. Am I to understand, Mr. Chairman, that you're suggesting that we should not follow the law and grant waivers?

Mr. DINGELL. I'm just trying to understand why you've got 28 tests that range practically the whole sweep of medicine here that are on your waiver list.

Mr. ROPER. We understood it to be an intent of Congress that there be a category of tests for waivers. Were we mistaken on that, sir?

Mr. DINGELL. Well, let's go to the tests. We've agreed as to what they might be. One, there has to be a very small risk of failure of the test. Two, that the consequences of the failure had to be relatively unimportant for the healthy individual. Is that correct?

Mr. ROPER. Yes, sir, that's what's been enacted.

Mr. DINGELL. All right, let's look at fecal occult blood. Now, if this isn't done right and you get a false negative, that won't serve as a warning, then, of the fact that the individual concerned might have colon cancer; is that right?

Mr. ROPER. Sure. It's a test that needs to be done correctly. It's a screening test. When I lived here in Washington several years ago, one of the local television stations had a program for promoting people doing this test at home. You may have been familiar with that.

Mr. DINGELL. Here's an article that appeared that says, as follows, "The tests demonstrated low sensitivity for detecting colorectal tumors, showing positive results in only 50 to 60 percent of asymptomatic cases."

Mr. ROPER. That has to do with the test. There's a question of it being certified as proper by our colleagues at the Food and Drug Administration in their licensing of it as a medical device.

Mr. DINGELL. OK, so I run in and get one of these tests. It shows I'm OK, but it's only 56 percent right because I don't happen to have a sort of standard form of this, and I go happily about my way and 5 years later, I die of colon cancer.

I'm curious if a waiver in this case is fully justified.

Mr. ROPER. If the accuracy is as low as you suggest, no, it's not justified.

Mr. DINGELL. Well, it does seem that maybe this got on the wrong list then; doesn't it?

Mr. ROPER. Again, I haven't seen the numbers that you cite. We'd need to look at that.

Mr. DINGELL. We will submit them to you. Now, let's go a little further here and let's look at some other things. You've got urine pregnancy tests.

A urine pregnancy test comes up wrong and somebody is going to run around thinking they aren't pregnant; right?

Mr. ROPER. Yes, sir.

Mr. DINGELL. Is that an important or an unimportant consequence of the failure?

Mr. ROPER. Very important information.

Mr. Dingell. I would say either to some young man who might have to leave town or some young woman who might have a problem, that's going to be a serious difficulty; is it not?

Mr. Roper. Yes, sir.

Mr. Dingell. Should this have gotten on the list?

Mr. Roper. It would be helpful, Mr. Chairman, if you would give us the list of tests you believe ought to be on the waiver.

Mr. Dingell. You're the expert. All I do is write the law. I call you up here to explain why you're not administering it properly. You've got to understand the difference of our respective positions.

Mr. Roper. I'm not sure I do, sir.

Mr. Dingell. I'm in the happy position of being able to criticize your failures and inaction. You can do it to me at election time. I'm pleased to report to you that's 1½ years off.

Let's talk about gram stain. A fellow has got a gram infection and you're running him through a whole bunch of tests to find out what's wrong with him. All of a sudden, you find that he doesn't happen to have a gram infection. Now, gram is a rather serious form of infection; is it not?

Mr. Roper. Actually, no, sir. Gram refers to a gentleman who invented a test. It's not a type of bacterium.

Mr. Dingell. We can figure that I'm wrong on this and that that properly belongs on this list.

Let's go to the next one. This is on your list, again, infectious mono. Somebody's got mononucleosis. If you get a wrong result on that, am I to assume that's showing up as an individual not having mononucleosis and that's a relatively unimportant consequence, or is that an important consequence?

Mr. Roper. It's an important consequence. In fact, to enlarge on my answer to you, Mr. Chairman, on the face of it, it is a simple understanding that if a test is worth paying real money for, it must have some utility and its results, therefore, must have some implications in the management of a patient. That would lead to the conclusion I take you to be pursuing; that is, no tests should be waivered.

However, I would assert that the Congress, in its wisdom, set up this category for a reason, and therefore, based on statistical probabilities, some tests might ought to be put into the category that you created.

Mr. Dingell. You have just made the interesting case that was made earlier by CDC, which told us that you ought not give any waivers.

Mr. Roper. Yes.

Mr. Dingell. I'm trying to understand which is the position of CDC.

Mr. Roper. CDC's current position is the same——

Mr. Dingell. You have made the statement that afflicted St. Paul on the road to Damascus. We inquired briefly to find out why that sudden change, but we have not been adequately advised as to what that might have been. We are now going down to try to find out whether you agree with your position as enunciated here, or the earlier position as enunciated by CDC.

Let us go down and discuss again infectious mono. Is it important to know that a fellow has got infectious mono with a fair measure of certainty, or can we sort of slop-jag around on this sort of test and say, well, it's really not an important test and if it doesn't come in with good results, we don't greatly care because he doesn't really need to know that anyhow? Which would be your position?

We should have here a test that can sort of disregard the second criteria that we have been discussing, or should we not?

Mr. **Roper**. I'm afraid I got lost there, sir.

Mr. **Dingell**. Is it your thesis that infectious mono falls in the category of a test which, if it doesn't come back correct, is not going to have significant adverse health impacts upon the individual who does not receive the proper test result?

Mr. **Roper**. It depends entirely on the clinical condition of the patient.

Mr. **Dingell**. Am I to assume then that you're telling me that the infectious mono can be important or unimportant for the fellow that's got it?

Mr. **Roper**. Yes, sir. It depends, again, on the clinical condition of the patient.

Mr. **Dingell**. I wonder if you can get broad agreement on that particular point from the people that have got infectious mono and are going to a doctor about it?

Mr. **Roper**. Excuse me, was that a question? I didn't hear you.

Mr. **Dingell**. Let's go to the next one, sickle cell screening, other than electrophoresis. Does that meet the second test, not really important to show whether they passed that test or not? It isn't going to bother them, either currently or later on? How did this test get on the list? Does it meet the criteria that we have agreed should be applied to waivers in both cases?

Mr. **Roper**. I think this is one that clearly ought to be re-thought.

Mr. **Dingell**. Do you want to come back and tell me that infectious mono waiver ought to be considered again or not?

Mr. **Roper**. It's the purpose of a public comment period to invite the comments from not only the Members of the Congress but the public at large on these issues. That's why we asked for it.

Mr. **Dingell**. Our inquiry here lies with regard to other matters; and that is, should these be on the waiver list. Now, happily, we're discussing it prior to the time that the waiver list comes out, but I'm trying still to come to an understanding of whether you have either a proper set of criteria for waiver lists or whether you have properly applied either the waiver list, or the criteria to those tests which are on the waiver list.

Mr. **Roper**. My position is that the Congress intended for there to be a category of tests granted waivers. That is why you put this section in the law.

We have invited comment from the public on what tests ought to be there, and we are now analyzing those comments and will shortly come forward with the final list.

Mr. **Dingell**. The Congress was not of the view that this use of the waiver test should be as a substitute for deep thinking and thought and careful application on the part of the agencies to whom we have entrusted the responsibility of carrying this out.

Mr. **Roper**. Nor is that our impression.

Mr. DINGELL. I am now discussing with you a list here, which I find interesting, which has been submitted to us as meeting the test. I am inquiring of you as to whether these meet the test.

I am distressed that they do not appear to me to meet the test and, in some instances, to you to meet the test. That is distressing. I find it also distressing that, in a number of instances, these things which I find do not meet the test you find do not meet the test.

I also read to you the earlier comments from CDC with regard to the fact that there should be no waivers. Of course, I am trying to find out whence come these waivers in view of CDC's recommendations.

I am asking you who it was that changed that earlier viewpoint held so firmly and, I thought, in such an erudite fashion by CDC. I would simply appreciate somebody informing me who it was that changed the views of CDC on this point.

Mr. ROPER. I am sorry. I was not there and cannot tell you who the person was. It is my position that the Congress wrote this section of the law for a reason and, therefore, intends there to be such a list.

Mr. DINGELL. Well, happily, we are, for once, in agreement here. We will return to this.

The Chair is going to recognize my good friend from Virginia.

Mr. BLILEY. I have no questions, Mr. Chairman.

Mr. DINGELL. Now, Dr. Wilensky, in your testimony, you state that HCFA will be regulating 300,000 to 600,000 laboratories when you implement CLIA '88. First of all, that is a very wide range.

You have a 100-percent difference if you take 300,000 or a 50-percent difference if you take 600,000.

I am trying to understand why you get such an extraordinary range and upon what you base that and why you do not have more accurate statistical information to arrive at judgments with regard to regulations.

Ms. WILENSKY. Well, the fact of the matter is, prior to this legislation, HCFA was required to regulate only those laboratories providing either Medicare or Medicaid testing or involving interstate commerce, and there were some 12,000 to 13,000 such labs.

We do not know all of the laboratories in the country, particularly when we include those that are in all of the doctors' offices and those that may be in malls or centers or whatever.

We have attempted to purchase lists and find other ways to try to get as full a listing of the potential universe, but it is when we do the provisional certification that we will, as a result of seeking out the individuals through the mailing list and notices in the newsletters, in fact, be able to know what the count is, and something about the kinds of tests that they provide and their personnel.

We have not previously been in a position to regulate them. We do not know how many there are and it is, in fact, a reflection of how monumental the task is that CLIA '88 represents to us.

Mr. DINGELL. Well, at the time the committee considered the legislation, the information that we received was that there were some 12,000 hospital and independent labs and 100,000 physician office labs.

Ms. WILENSKY. I believe that is a serious underestimate.

Mr. DINGELL. Pardon?

Ms. WILENSKY. I believe that is seriously underestimating the number of physician office labs. The 12,000 is correct. In part, it depends on how one defines laboratory testing.

The kinds of tests that are being referenced will bring in very large numbers, but we will only know, in fact, when physicians who are doing tests that are now included under CLIA indicate they want to continue doing testing.

It is possible that some physicians who are currently doing testing will, for whatever reasons, choose to not pursue that in the future. The number may change. We will know for sure when we have the provisional licensing.

Mr. DINGELL. The information the committee received from HHS came from a study which was done by Inspector General Richard Kusserow.

Now, have you folks performed any study to come up with the numbers that you have given us, or has this been received from something on high?

Ms. WILENSKY. In our attempt to get the potential universe, we have looked to mailing lists from groups that are involved with what we think may be laboratories to get all the individual names.

We have now a need to know this in a way that did not exist before, and I think we will have this information as a result of the process we are undertaking for the provisional licensing.

I do not believe Mr. Kusserow was able to get this information either. It simply wasn't available. I'm sure he did the best he could.

Mr. DINGELL. Can you give us any appreciation of how long it will be before you have these numbers?

Ms. WILENSKY. We are going to proceed with the provisional licensing as of July 1st, and we will have it completed during the course of the next, I think, 6-to-12-month period.

Of the licensing that we are doing, we assume that about half of it will occur sooner than that, probably about the next 6 or 7 months.

Mr. DINGELL. Should we wait until we receive a conclusive judgment as to how many people there are involved?

Ms. WILENSKY. No.

Mr. DINGELL. Should we proceed with vigor on the regulations?

Ms. WILENSKY. I think it will be helpful in terms of doing some of the impact analysis. There will be some part of the impact analysis that will, of necessity, be based on estimations, but no, I do not think you ought to wait until you have that information.

We can if you wish, but we were not intending to.

Mr. DINGELL. I may have a very curious view of what it was we had in mind when we enacted the legislation, but I had the distinct feeling that my colleagues and I thought that the purpose of enacting this legislation was to stop bad laboratory testing.

Is that the purpose that you see behind this basic legislation, ladies and gentlemen?

Ms. WILENSKY. To stop bad testing by the mechanism of bringing it all under Federal regulation, which assumes a certain level of activities, but the ultimate purpose was to provide better-quality laboratory services.

Mr. DINGELL. OK. Am I to consider that this legislation in any way was adopted for the convenience of the laboratories?

Ms. WILENSKY. Certainly not.

Mr. DINGELL. So, having come to that conclusion, that we are trying to stop bad laboratory testing, we are trying to upgrade the quality of laboratory testing. Should I be prodigiously distressed if we drive out of the business some of the people that this committee, in its oversight hearings, earlier found engaged in slipshod testing of people and performing important medical tests which misled the people for whom the testing was done?

Ms. WILENSKY. No, you should not be concerned about that, but the question is whether it will drive out other laboratories that are providing necessary services and quality health services. That is the kind of comment that we were hearing during the comment period.

Mr. DINGELL. I have no desire to have responsible laboratories penalized by this legislation, but by the same token, I find myself concerned that, 2½ years after the enactment of the legislation, nothing has gone into place, with the exception of mailing a bunch of—well, no, you have not mailed the certificates yet—that nothing has been done to deal with the problem of inadequate medical testing, except the formulation of what a risk is that, in colloquy between Dr. Roper and I, appears now to be somewhat questionable as a matter of policy.

Now, since the regulations establishing standards are not finalized, how are we or the laboratories or you or the health industry going to plan for the growth in volume that they expect to experience once the regulations do become final?

Ms. WILENSKY. I do not understand the intent of the question.

Mr. DINGELL. Well, maybe we will just pass that one on.

Now, Dr. Wilensky, we will be hearing from Dr. Kroger, with the Commission on Office Laboratory Assessment, later today. As you know, that institution, called COLA, is the only accrediting organization that specifically provides accreditation for physician office labs.

Dr. Kroger is going to tell us that the number of doctors applying for accreditation shortly following CLIA '88's passage has fallen off sharply over the last year, and this appears to be related to the uncertainty within accrediting organizations and the regulated industry as to whether they will not be or will be approved by HCFA.

Now, do you find that surprising?

Ms. WILENSKY. No, I do not find it surprising. I think we have had raised to our concern that the standards that we have, in the interest of having high quality, are going to discourage a number of physicians and other labs from continuing practice.

Mr. DINGELL. Thank you.

The gentleman from Oregon.

Mr. WYDEN. Thank you, Mr. Chairman.

Just very briefly, I would like to ask the Chair's permission to insert into the record a chronology in terms of the events over the last few years with respect to clinical laboratories, because not only is this chronology especially helpful in terms of an overview of the last 6 years, but the very first, extremely important point made by the chairman a minute ago with respect to physician office labs. I would just read that, in December of 1985, the Omnibus Budget Reconciliation Act passed with a requirement for a report on minimum standards for physician office labs.

That was due in 1 year, and as far as I can ascertain——

Mr. **Dingell**. It has not been accomplished.

Mr. **Wyden**. Mr. Chairman, I would just ask Dr. Wilensky, has that particular report, which was ordered by the Congress in December of 1985, has that ever been submitted?

Ms. **Wilensky**. About a year ago, June of 1990.

Mr. **Wyden**. I am not aware that this report has been submitted. Does one of your people even have one of these?

Ms. **Wilensky**. Well, we will make sure that your office receives another copy.

Mr. **Wyden**. Were there standards there for physician office labs in that report?

Ms. **Wilensky**. I do not know.

Mr. **Wyden**. Do any of your associates know?

Ms. **Wilensky**. Not specific standards, is what I am told.

Mr. **Wyden**. Then I think the point that I am concerned about remains. The Congress, in 1985, passed a requirement for a report specifically on minimum standards for physician office labs due in 1 year. Chairman Dingell raised this point with you. You have just told me that, in 1990, something was submitted to the Congress involving physician office labs, and we are happy to see that. But I do not know of any report on minimum standards for physician office labs, even though the Congress directed that it be done in December of 1985.

Ms. **Wilensky**. Well, certainly, by the time 1988 came and we were actively involved in setting these tests and complexities and personnel qualifications, we would have wanted to have that regulation be consistent with this report. I do not know what happened with the report; but I would assume until we have settled the issue that is involved in the CLIA '88 regulations, we would not be having an independent assessment done of that order.

Mr. **Wyden**. Well, I think the point Chairman Dingell is making remains. We still do not have a basic handle on the issue of physician office labs, either in terms of numbers or standards. I am requesting a standard specifically. Congress did direct, in December of 1985, that we get some of this information. Let me ask you one question, again, on the point, of an incremental measure.

I have been able to find some of the comments that Mr. Kusserow has made, with respect to cholesterol screenings. I will just read to you from one of the newspaper articles that I found. This was on the basis of 10 States that he looked at, and the District of Columbia. I quote here from one of the newspaper articles. It says: "Some of the tests were conducted under unsanitary conditions by people who had bloody needles and specimens lying around. Some of the personnel gave tests and handled money without wearing rubber gloves or washing properly."

Here Mr. Kusserow is quoted. "Given today's concern for the spread of AIDS and hepatitis, these findings are particularly disturbing."

Given the fact that this was said over 1½ years ago, is there any reason why the department shouldn't move immediately to go after something that has been clearly documented like this?

Ms. Wilensky. Again, I think the problem, Mr. Wyden, is that the whole issue of how to treat various tests depends on having agreement on the complexity model, on where tests ought to go, the kinds of personnel that ought to be associated with it.

Now, Mr. Dingell, to my ears, was also, as Dr. Roper suggested, making it sound as though he personally did not believe there was such a thing as a properly waivered test. We have received, among these 60,000 comments, an enormous variation, in terms of people who, I believe, have some understanding and standing in the scientific community, that give us very very different advice. I think we can come forward with a good regulation. The notion that it is just very clear what it should be and that all reasonable people agree about this is just very far——

Mr. Wyden. Couldn't we, at a minimum, have a rule that would address the concerns Mr. Kusserow was talking about? For example, making sure that people who give these tests in shopping malls, where you are seeing a huge amount of growth, that they be required to wash properly, that they be required to use clean needles? These are the things that Mr. Kusserow found over 1½ years ago, and yet there has been no action taken by the Government. Mr. Kusserow says, and I just read you the quote, "given the concern about AIDS and hepatitis," he finds it disturbing.

Ms. Wilensky. Well, again, I think the idea on this is that you are taking one test out of hundreds or thousands of tests. We could deal with this through the regulation process. As you well know, there is nothing that the administration can do without going through the normal regulatory process, as defined by the APA, where we put out proposed rules, we get response and then we act.

Mr. Dingell. Would the gentleman yield?

Mr. Wyden. I would be happy to yield.

Mr. Dingell. Let's talk a little bit about that. They need to draw blood for the cholesterol tests, right?

Ms. Wilensky. These are, generally, licensed by the States. I do not know who they license to draw blood. We do not have national regulations of physicians. We do not have national regulations of nurses. Now, I do not know, maybe you gentlemen would like that, but we do not normally do that now.

Mr. Dingell. Let's take a little look at this. Is this a test that ought to be on the waiver list?

Ms. Wilensky. I rely on advice for the proper placement of testing from my scientific personnel.

Mr. Dingell. Maybe you ought to give us your comments, Dr. Roper. Should this be on your waiver list?

Mr. Roper. No. No, sir.

Mr. Dingell. Should some guy be in a shopping center, sticking you with a needle and then sticking the next guy that comes along with a needle, and sticking some other guy along with a needle? You ought to have at least minimum standards for the fellow who is going to be doing the sticking with the needle, to make sure he is not using the same needle on everybody, shouldn't you?

Ms. **Wilensky**. There is nothing you can do with cholesterol testing. I mean, the needle going from one to another, is irrespective of, I would think, what the test is.

Mr. **Dingell**. We sort of hope that is the case, don't we?

Ms. **Wilensky**. We certainly do.

Mr. **Dingell**. Do we know it is the case? If you have some blockhead who does not know much about sanitation doing that, you just might not get that result?

Ms. **Wilensky**. That is correct.

Mr. **Dingell**. If the guy before you was an AIDS patient, you might not be too enthused about the process; isn't that right?

Ms. **Wilensky**. That is correct.

Mr. **Roper**. If I could make a general point, Mr. Chairman? The reason that shopping mall labs, or whatever you want to call them, are not regulated by the Federal Government is this law, which you passed, is not yet fully implemented because of the regulation.

Mr. **Dingell**. Well, that is why you are here talking to us, because you have not implemented it yet.

Mr. **Roper**. Well, if I could be then responsive to Mr. Wyden. If I understand him, we could pull out shopping mall labs and do a separate regulatory effort, but we are attempting to do what the law, in general, requires and that is go forward with a general regulatory effort.

Mr. **Wyden**. Dr. Roper, you are very up on the law. The law specifically provides for incremental——

Mr. **Roper**. Sure.

Mr. **Wyden**. Implementation. I use this example only because, in a number of our discussions earlier, both you and Ms. Wilensky, talked about anecdotal evidence and less than full documentation for some of these problems. This involved a hearing in November of 1989. Mr. Kusserow took, at my request, an extensive look at this particular area, cholesterol testing. He raised serious problems about bloody needles being left around, personnel giving tests who were not trained, people handling patients without washing properly, and not knowing how to calibrate the machines. These were findings that he made as Inspector General. So, it seems to me, there is no documentation issue. At least, we could have minimum standards so people do not leave bloody needles lying around and people would wash up before they performed tests.

Ms. **Wilensky**. Again, this just came out at the end of 1989. In May of 1990, we came forward with what we thought was a proposed rule that would have gone after all of the tests. Now, obviously, as a result of the kind of response that was provoked, we have a much more serious amount of work that we are in the process of doing. We could have then said, all right, well, we cannot handle all of this, we can just go out and pick a couple of areas. That was not our sense of what it was that we were being asked most strongly to do by Congress.

You have been kept informed, in a very full way, of our activities and I think you are receiving the reports that I provide every 2 weeks, about exactly where we are in this process. We could have stopped what we were doing and tried to go only through this one area. That really would not have seemed to me to be a good response to the intent that you had or our intent to try to resolve this.

Mr. WYDEN. Well, on that point, would it have been necessary to stop the development of the overall plan to implement CLIA in order to get some public protection in a number of key areas that your own Departmental officials have found? As I said, I am just reading to you from one of the newspaper articles that highlights Mr. Kusserow's concerns. It would seem to me that that could have been addressed, while at the same time, you could have gone forward with the overall plan. Is that not the case?

Ms. WILENSKY. Mr. Wyden, when you put out Federal regulations in areas in which the Federal Government has not operated before, whether it is appropriate or not that the Federal Government has not been operating there before, you get a lot of comments. The notion that we could have just whipped out this regulation to go after shopping mall testing and not had to go through some serious thought about what we do once we go into that.

What is it we want to do now? Do we just want to prevent these gross violations of common sense and hygiene that are going on? Precisely what do we want to do? Who can do it? Where can it go? What kind of standards? This is not something that you just whip off in 1 or 2 weeks and then it goes on its way.

Mr. DINGELL. Would the gentleman yield?

Mr. WYDEN. Yes.

Mr. DINGELL. Would you be mailing any of these $260 certifications or accreditation to any of the shopping mall lab operators?

Ms. WILENSKY. I assume that we will initially send out a listing to every group, to indicate whether they want to come into the certification program, and then we will begin the certification as rapidly as we can.

So, initially, yes. It is the only way we know who is out there and what they are doing. As promptly thereafter as we can, we will start surveying them. We do not have any other way to proceed.

Mr. DINGELL. So, for $260 they get accreditation just like the guy who runs the high class laboratory at Massachusetts General Hospital?

Ms. WILENSKY. Until the first inspection occurs. They, of course, are operating now. We are not changing anything that they are not doing now. We are trying to proceed in an orderly way, having funds to allow us to proceed in collecting information, so we know something about who is providing what test. They will come under this requirement, unless they go out of business. Everyone who performs lab tests will be under this requirement. It is a first step to try to have us go forward.

Mr. DINGELL. Well, I am trying to figure out whether we are better off having these fellows who run these shopping center lab tests have a $260 certificate from HHS or better off having them not have a $260 certificate from HHS. Do we know which is the better situation?

Ms. WILENSKY. We do not know anything about them until we get the information back so we know how to proceed.

Mr. DINGELL. Thank you.

Mr. WYDEN. Mr. Chairman, I would just ask unanimous consent that both the chronology of this 6-year odyssey involving clinical labs, plus this New York Times articles, which seem to me documented clearly the problems with cholesterol tests, could be inserted into the record at the appropriate point.

Mr. DINGELL. The Chair thanks the gentleman. Well, Ms. Wilensky, Dr. Roper, Mr. MacRae, we thank you for your kindness to the committee today. It has been a very enlightening discussion.

The Chair announces that our next panel will be composed of Dr. Herbert W. Dickerman, M.D., New York State Department of Health, Albany, New York.

Dr. Dickerman, you are certainly welcomed to the committee today. You heard the Chair qualify witnesses. As you know, all witnesses are required to testify under oath. Do you have any objection to that?

Mr. DICKERMAN. None at all.

Mr. DINGELL. Doctor, the Chair notes, for your assistance, that copies of the rules of the committee, the subcommittee, and the House are there at the witness table to assist you in knowing both your rights and limitations on the power of the committee.

Doctor, the Chair advises that, under the rules, you are entitled to be advised by counsel during your appearance here if you so choose. Do you wish to be advised by counsel?

Mr. DICKERMAN. No, sir.

Mr. DINGELL. Very well. Then, if you have no objection to testifying under oath, will you please rise and raise your right hand?

[Witness sworn.]

Mr. DINGELL. You may consider yourself under oath.

Doctor, you are recognized for such statement as you choose to give.

TESTIMONY OF HERBERT W. DICKERMAN, DIRECTOR, WADSWORTH CENTER, NEW YORK STATE DEPARTMENT OF HEALTH

Mr. DICKERMAN. Thank you for the opportunity to share in discussions of the critical issues surrounding the Federal Government's role in assuring the quality of clinical laboratory testing.

As the Director of the New York State Department of Health, Wadsworth Center, the laboratory arm of the Health Department, which has had a long and distinguished history in regulatory oversight of clinical laboratories, I would like to review the issues before the committee and to comment on the Omnibus Budget Reconciliation of 1987 and CLIA '88.

Before I begin, I am not a political scientist, but I do recall somewhere that States could generate programs which were to be models for Federal legislation later on. Wisconsin did so in worker's compensation, other States in conservation.

I would like to think that New York State has done this in the area of clinical laboratory supervision.

In particular, I want to present the Department's views on the importance of clinical testing, the changes in the content of the regulatory programs, and response to the recent innovations in clinical science, New York State's present accreditation activities, our position on OBRA '87 and CLIA '88, and experience that we have been having in seeking approval of our proficiency testing program from HCFA and the impact of the delayed implementation of OBRA '87 and CLIA on both the regulatory and regulated organizations.

I want to make one thing abundantly clear: If there were no CLIA, it would not affect the laboratories in the State of New York one iota, with the exception of physician-owned laboratories. If there were no CLIA, the level of safety and proficiency within the laboratories would be exactly what they will be after CLIA.

So, CLIA has no impact upon us from the standpoint of any of our duties involved in operating a very large clinical laboratory supervisory program. What it does do is cause us an awful lot of headaches.

I would like to read from the New York State Article 5, Title 5, Laboratory Improvement Act, which was adopted in 1964.

> The proper performance of laboratory services is a matter of vital concern affecting the public health, safety, and welfare. Clinical laboratories and blood banks provide essential public health services in aiding health care providers by furnishing information valuable to the diagnosis and treatment of disease. The improper performance of a laboratory procedure may induce an erroneous diagnosis and contribute to the selection of an inappropriate method of treatment resulting in prolonged and unnecessary hospitalization, injury, or even death. The protection of the people of this State requires affirmative action to ensure that the performances of laboratory and blood-banking services meet high standards of public health care.

I can only add that the need for regulatory oversight of clinical testing is more imperative today. In over a quarter-century since the enactment of our legislation in New York State, the number and diversity of clinical laboratory tests have increased dramatically.

An example in the area of clinical chemistry illustrates the point. In 1960, laboratories that were doing clinical specimens tested for 38 different chemical analytes. In the 1990's, the testing arsenal in just this one single area of clinical sciences had grown to more than 125.

In 1960, the clinical laboratories conducted about 100,000 chemistry assays a year. By 1990, this number had risen to more than 1.7 million assays per year.

Today's health-care professionals rely far more than their colleagues a generation ago on the clinical information generated by laboratory testing to establish diagnosis and therapy. One measure of the importance of clinical testing in the practice of modern medicine is the increase in POL's, or physician office laboratories. In the July 1988 issue of the Journal of the American Medical Association, at least 20 percent of all testing performed in the United States occurred in POL's. Approximately 70 percent of group-practice physicians and approximately 90 percent of primary-care physicians perform some form of testing. The article projects that the volume of testing in POL's will increase by 15 percent each year over the next several years.

Clinical laboratory testing is also an essential component of preventive medicine. I need not remind this committee that the numerous and highly-publicized quality-control problems associated with false-negative Pap smears contributed to the CLIA '88 enactment. Screening for HIV, hepatitis B and C viruses have greatly improved the safety of transfusion by reducing significantly transmission of these agents. The cumulative data gathered from screening tests have been of tremendous value in detection and early treatment of colon-rectal cancer, diabetes, coronary disease, etcetera.

A recent study in the Archives of Internal Medicine showed that adults, studied in this prospective investigation, that the numbers undergoing serum cholesterol testing increased from 35 percent to 65 percent during the years 1983 to 1990. A mere decade ago, glucose monitoring and cholesterol screening at health fairs in local shopping malls were objects of public curiosity. Today, we in New York State review and approve over 2,000 applications each year to conduct laboratory testing in these locations.

To summarize, laboratory testing in all settings is essential to the practice of medicine and is of critical importance for the prevention, diagnosis, and treatment of disease.

Now, clinical testing depends upon two factors: instrumentation and the individuals performing the testing. Both are subject to error. Regulatory oversight of laboratories provides the most effective mechanism to ensure competent performance of both personnel and instrumentation and thereby safeguard public health and safety.

Clinical sciences are a dynamic field, with new techniques or instrumentation constantly appearing and becoming commercially available. Since the introduction of the New York State regulatory program in the 1960's, two quite different trends in clinical testing have emerged. More highly complex tests have been introduced, such as those utilizing DNA probes to screen for congenital or inborn genetic diseases. These procedures are highly specialized, require extensive interpretative analysis from skilled laboratory personnel and are available primarily in tertiary care institutions and research laboratories. At the same time, however, many tests have been simplified and automated. So, they can be performed readily by individuals with limited or no formal training.

So, regulation cannot be static. In order to maintain an effective oversight of this rapidly-changing area of applied science, we in New York State have attempted to meet the challenges of the new tests and technologies by continual review and modification of our regulations and reassessment of our regulatory program. When we initiated proficiency testing in the early 1970's, laboratory permits were offered in 11 specialties and 20 test sub-specialties. Today, the numbers are 20 major test categories and 50 sub-categories.

I want to emphasize one point about proficiency testing which may not be so apparent to people who are outside the field. When we proficiency test a laboratory, we are assessing the optimal not the routine capabilities of a laboratory, because facilities can readily identify and segregate proficiency test specimens for special processing.

To compensate for this and under, really, the suggestion of our then-Commissioner Dr. David Axelrod, we try to come up with ways to get around this. We utilize hand-carried test samples in several categories. Field representatives of our evaluation program directly convey samples to the laboratory. These test samples must be analyzed in the presence of a field representative.

To improve that program further, we are investigating the use of retro-testing in categories such as chemistry, cytogenetics, and microbiology. In retro-testing, portions of the actual clinical specimens and patient test results previously reported by a laboratory are obtained by our field personnel during onsite laboratory inspections. These materials are then analyzed within the Wadsworth Center and the patient test results compared with those obtained at our laboratories. In this way, we can evaluate directly and effectively the quality of testing conducted routinely in such facilities holding State permits.

New York was the first State in the Nation to initiate a certification and licensure program for laboratories. Since 1972, New York has been the only State licensing agency whose laboratories are deemed to meet CLIA '67 requirements.

This is a consequence of HCFA's recognition that New York program standards are equal to or more stringent than the Federal requirements, which is really going to get to the nub of the issue, because in our State, at least, whenever we do local exception, we do it on the basis that the program that is requesting this is equal to or more stringent than our program. We seem to be confronting something at HCFA where we have to become equal to or less than our program in order to meet their standards.

All hospital-based and commercial laboratories and blood banks or any out of the State which test specimens originating within New York State are included in our program, and we do not accept the results of any other State's proficiency testing programs.

We are under contract to HCFA to conduct all Medicare surveys of non-hospital-based laboratories within the State and all laboratories and blood banks within New York City that receive Medicaid reimbursement.

In 1990, 941 clinical laboratories and blood banks, including collection stations, were granted New York State laboratory permits. Approximately 150 clinical facilities were inspected for Federal intrastate licensure or certified for Medicare.

I bring this out because I am not sure that we have ever been contacted in regard to our total census of laboratories within New York State, which roughly represent about 10 percent of the total.

Our regulatory oversight program includes evaluation of the credentials of laboratory personnel, from director to technologist; onsite facility inspection to assess methods, procedures, instrumentation; proficiency testing to evaluate critically the accuracy and the liability of test performance, at the optimum; corrective mediation of sub-optimal performance; and continuing education of laboratory personnel; and finally—and this separates from everybody else in this particular form of activity—enforcement to ensure public health and safety.

Under State regulations, individuals seeking to direct clinical laboratories and blood banks which test specimens must apply for a certificate of qualification by submitting their credentials for evaluation. During 1990, we reviewed and approved 850 initial applications. The laboratory director—and this is key to our program—is held responsible for all technical aspects of a laboratory's operation, including staff qualifications.

Onsite inspection of State-permit-holding facilities is the second key element in the program. We employ 12 field surveyors who are broadly trained in most aspects of clinical laboratory testing. Most are certified medical technologists. Inspections afford a means to monitor directly methods, procedures, and instrumentation employed in the routine testing of a facility. The surveyors also assist laboratory personnel in problem-solving and provide training and information on innovations. If deficiencies are found during inspection, facilities are notified and required to submit a plan of correction. Failure to correct the deficiencies may result in non-renewal of the laboratory's permit and/or revocation of the director's certificate of qualification.

Our testing program requires clinical laboratories and blood banks failing testing in one or more categories, either as a result of one test event or cumulative test scores, to cease testing patient specimens in the affected categories or for specific analytes. New York's program seeks to combine effective enforcement with remedial education in order to improve the capabilities of the laboratories. Failing facilities must identify the cause of failure and take corrective action. The training can be provided either at the Wadsworth Center or at a permit-holding facility convenient to the failing laboratory.

Laboratories successfully completing remediation and subsequent special testing are allowed to resume patient testing. Detailed critiques describing acceptable results, summarizing the participating laboratory performance, and providing relevant technical information are published by our professional staff and distributed to the participating facilities.

An example from our experience in testing the role of remediation—I am not sure this was brought out in the earlier testimony—in promoting better laboratory testing: First of all, sometimes when we have started a category, we have noticed, that, yes, indeed, some laboratories dropped out of the program. They realized that the norms at which they would be examined would be too hard for them to sustain.

In the first testing event—this was in microbiology—more than 50 percent of the laboratories could not identify the microbial pathogens satisfactorily. However, after only 18 months, 97 percent were able to meet that challenge.

I would like to talk about enforcement, because I feel very strongly about this. It is the final key ingredient. In 1990, 93 investigations of clinical laboratories and laboratory directors were conducted by the Wadsworth Center, resulting in enforcement actions against 30.

These included closing of 6 laboratories, disapproval of permit applications at 3 laboratories, issuance of conditional or restricted State permits to 10 laboratories, and pending enforcement actions against 11 laboratories. Indeed, we have found that there is a basic low percent of our total laboratory population which have no intent of providing good laboratory care, which have no intent of meeting any standards, and we take them out of business.

New York State's regulatory program is funded through fees based on the total gross annual receipts of all clinical facilities holding State permits. Last year, we reported total gross annual receipts of all facilities with New York as approximately $1 billion. Each clinical laboratory or blood bank pays a proportionate share and the program cost based on its receipts from testing specimens from New York.

We have also served at the Wadsworth Center as a consultant to HCFA in developing the initial proposal for proficiency testing regulations mandated by OBRA 1987. We critically evaluated the proposal when first published as draft regulations in 1988, and provided extensive and specific technical suggestions which you will find in my Appendix B to my testimony. However, HCFA largely rejected our recommendations and those of other States and professional organizations as borne out by the final regulations published in the Federal Register on March 14, 1990.

As discussed earlier, New York State has been recognized for 19 years by the Secretary of Health and Human Services as having program standards equal to or more stringent than the Federal requirements. We are also under contract to HCFA to evaluate and certify facilities for Medicare reimbursement. Therefore, when initially applying for HCFA's approval of our proficiency testing program, we submitted documentation describing our present program. We then discovered that HCFA would not approve any aspect of our program more stringent than its own. For example, a greater number and diversity of test analytes; use of handcarried proficiency tests; shorter notification period in case of violations; additional requirements for signatures on attestation statements. We have this all documented in our Appendix C.

Furthermore, in attempting to achieve uniformity in proficiency testing, HCFA has failed to take into consideration important differences among specialties and subspecialties in clinical science. I will illustrate this with the following examples:

Frequency of test events. HCFA requires quarterly testing in all specialties and subspecialties, except for two. New York States's program calls for frequency ranging from one every 2 years to five times a year, depending upon the specialty. While testing four times a year is feasible and justified for a specialty employing automated instrumentation, such as clinical chemistry, it is not justified and administratively problematic in a labor-intensive specialty such as mycology which requires time-consuming manual techniques. New York State's program presently stipulates five test events per year for clinical chemistry but only two for mycology. We vary with the technology in this.

Scoring of test events. According to HCFA's regulations, satisfactory performance requires a score of 80 percent or higher in each testing event for almost all specialties and subspecialties, including detection of antibodies to HIV and hepatitis B virus. In other words, a laboratory would meet HCFA standards even though it identified incorrectly 20 percent of positive test specimens for these infectious agents. Obviously, we require 100 percent when we deal with HIV and hepatitis B.

Selection of test specialties and analytes. HCFA's program is silent about the requisites for several areas of clinical sciences. For example, there are no performance standards, nor is there proficiency testing, in the areas of genetics or cellular immunology, which is ironic, because we were involved with a laboratory in Virginia who does work on patients in New York State, and they submitted to us that HCFA said that they had to enroll in a proficiency testing program, and gave them a list of tests and States and private organizations that were capable of doing that; but if you look through the list, cytogenetics is not on the list. So they are told to enroll in a proficiency testing program for which there is no subcategory which is going to be tested.

HCFA's proficiency testing also omits several analytes, like phosphorus and salicylate, which are routinely evaluated in clinical chemistry laboratories.

Furthermore, other analytes are too restrictively classified. Although the FDA has approved the clinical use of alpha fetoprotein testing for prenatal screening, proficiency testing for that purpose was specifically excluded by HCFA. Now, that is a very interesting point, because we have to deal, at the State level, when the FDA produces a test for general use, and as a matter of fact when the FDA released the test for HIV, it essentially led to a whole fundamental approach to how we were going to handle HIV in the State of New York, and as you know, that is a major problem for us. It led to counseling, it led to anonymity, it led to all sorts of things that the laboratory along with the rest of the Department got into, because we were confronted with this test that not only had the ability to help, but that had the ability to hurt.

Alpha fetoprotein is very much a similar test. When used in the prenatal population, it is there for a diagnosis of spinal defects. It cannot be done willy-nilly. It cannot be done just like any other tests. There are certain built-ins you have to have to do this test. You have to get the positive results, it has to be in the right range at the right time of pregnancy. It requires at this point you either go for an echo, and ultimately for an amniocentesis. It has to be repeated. In other words, there is a built-in sequence of events if you have a positive at the right time to ensure that the child does not have a spinal defect. It cannot be just handed out. You have an alpha fetoprotein of such a value, and that you are going to interpret. We did not think it was appropriate that HCFA would ignore this relatively large area of testing, and restrict it to oncoproteins.

Now, what about the impact of implementation on regulatory and regulated organizations? I want to come back to my first statement. If tomorrow HCFA went away, OBRA went away, CLIA went away, we would not care. It would not make one iota of difference to us in New York State, except for physician-only laboratories. So that is not a problem for us.

We appreciate the constraints under which HCFA regulations have developed. Delays in the implementation of OBRA 1987, CLIA 1988 have had a significant detrimental effect. I am a professional bureaucrat. I know what a bureaucracy is like. I know it is difficult to move through these things. It is not a simple task to make these determinations. But after this incident, I am going back to reading Franz Kafka.

Mr. WYDEN. Doctor, just in the interests of time, and we very much appreciate all the cooperation you have shown the subcommittee, could you perhaps summarize any principal concerns that you have, and then we will have some questions for you?

Mr. DICKERMAN. I can only speak for my own position, and I am sorry if I have overstated my time. I did not mean to.

There are a few points that we are most concerned about. We do not think that—there was never an attempt on HCFA—we had had a program in place in the State of New York since 1964. There was never an attempt for them to come up and say well, how does the program really work? Why didn't they come into our lab; why didn't they come into our regulatory units; why didn't they spend time? We have had the field experience. They are talking about getting into something which is new and big and large. We are not exactly a peanut. They could have taken steps prior to full implementation. There could have been a census of laboratories.

We have a contract now with FDA to look into the number of POL's in the State of New York that we submitted a grant for, and were a participant in. We do not know. We do not honestly know what every physician in the State of New York is doing in his office. We are trying to find out. We should know that. That is data.

Again, I do not think the consultation with the professionals in the fields—and we have run into that, I do not have to tell you, because the cytologists will be in to talk to you and the cytopathologists, and I am sure they will give you their message a lot clearer than I will.

Otherwise, we really resent the fact that our interpretation means equal to or better than. We do not want to reduce our program to mediocrity in order to be accepted within the HCFA program.

Thank you.

Mr. WYDEN [presiding]. That is very helpful, Doctor. Chairman Dingell had to go, but he wanted me to assure you just how much he appreciated the cooperation that you have shown the subcommittee. It is quite clear that your program is very much a hands-on kind of effort.

Now, you raised some basic questions about the fundamental elements of HCFA's proposed regulations—for example, the feasibility of testing each specialty four times a year.

Another example you used was that HCFA's regulations would allow a 20 percent failure rate, even for the HIV virus.

Is there any scientific basis for these kinds of proposals?

Mr. DICKERMAN. I think it is judgment. I think it is a judgment call. Just like in medicine there is such a thing called "clinical judgment," I think here you have a judgment.

To us, the relative simplicity of the test would indicate that a good laboratory would never fail if they were looking for HIV serology or for hepatitis C or B.

On the other hand, we did change a lot of things as a consequence of our interactions during the enactment of CLIA 1988. We changed our approach to cytopathology, which may not be borne out because we will not be here for those discussions. We individualized. We take boxes of slides into a cytotechnology lab, and in the presence of our inspector, they must be screened by the personnel who are there. We have also licensed our cytotechnologists, or essentially registered them, as a consequence of your hearings. So that we used to leave the responsibility to the laboratory; now we are putting the onus, to a certain extent, on the cytotechnologist. We know who the good ones and who the bad ones are and who have to be remediated; and I think if anything came out of those meetings as far as we are concerned, that was the most substantial increase in making cytophathology a more controllable or more testable area. I was very pleased about that.

Mr. **Wyden**. Based on your observations of HCFA's performance in the past, Doctor, do you think it is realistic to expect that HCFA would issue the final regulations by early next year?

Mr. **Dickerman**. No.

Mr. **Wyden**. On this point of the incremental approach, and understand that this is considered very much an open question being discussed by the members and the like, is that something that you think ought to be explored so that you can go forward and start attacking this even on that basis?

Mr. **Dickerman**. I think in the area of physician-only laboratories, it is the only way we are going to be able to do it. We do not even have a program there. We have been waiting for the program to emanate from Washington.

Frankly, it is going to be very difficult. It is going to be very difficult. If you walk into a commercial laboratory, a hospital laboratory, there is a certain protocol, there is a certain program, there is a certain expectation. I do not know if we are going to have the same thing when we go into the physicians' offices.

Mr. **Wyden**. Any other measures, Doctor, in the interim, that you think would be appropriate?

Mr. **Dickerman**. I would like for them to accept what is on the books already and not give us a fit. That is one thing I would like. I like when they say, well, we are getting started in this field, you know; that is a little hard for us to take.

Mr. **Wyden**. You have been very helpful, and we appreciate your extensive cooperation and assistance.

I know that the subcommittee will be talking to you in the days ahead.

Mr. **Dickerman**. Thank you.

Mr. **Wyden**. Our next panel is Dr. Raymond Scalettar, a member of the Board of Trustees, American Medical Association, Washington, D.C.; Mr. Alan H. Magazine, President, Health Industry Manufacturers Association; J. Stephen Kroger, M.D., Chief Executive Officer, Commission on Office Laboratory Assessment, Silver Spring, Maryland.

If you gentleman would come forward, we have certain formalities to address.

Please be seated.

It is the practice of the Subcommittee on Oversight and Investigations to swear all the witnesses who come before the subcommittee. Do either of you three, Dr. Scalettar, Mr. Magazine or Dr. Kroger, do any of you have any objection to being sworn as a witness?

Mr. **Magazine**. Mr. Chairman, Mr. Edward Allen, our General Counsel and Vice President, will be joining me, if that's permissible.

Mr. **Wyden**. Yes. Just so we are clear, all witnesses have an absolute right to counsel but counsel is here to advise a witness and will not be sworn because counsel is not expected to testify.

Dr. Scalettar, Mr. Magazine, Dr. Kroger, we'll swear you all at this time.

[Witnesses sworn.]

Mr. WYDEN. Gentlemen, as I mentioned, right to counsel is absolute before this subcommittee.

Do any of you desire to be represented by counsel today?

Mr. SCALETTAR. Yes.

Mr. WYDEN. OK, let us make sure. Dr. Scalettar of the Board of Trustees of the American Medical Association, who is your counsel?

Mr. SCALETTAR. Ms. Janet Horan——

Mr. WYDEN. Very good. Mr. Magazine or Dr. Kroger, do you either of you gentlemen desire to be represented by counsel?

Mr. KROGER. Yes, sir. Mr. Edward Allen.

Mr. WYDEN. Mr. Edward Allen is well known to this subcommittee and it's good to have him at the table today.

We are going to make your prepared statements part of the hearing record in their entirety and if it would be possible, in the interests of time, to summarize your principal concerns, that would be helpful.

Your prepared remarks, of course, will be entered into the record in their entirety and that could save a bit of time and allow for questions.

We welcome all of you.

Dr. Scalettar, we'll begin with you.

TESTIMONY OF RAYMOND SCALETTAR, MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; ALAN H. MAGAZINE, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; AND J. STEPHEN KROGER, CHIEF EXECUTIVE OFFICER, COMMISSION ON OFFICE LABORATORY ASSESSMENT

Mr. SCALETTAR. Thank you. Thank you, Mr. Chairman and members of the committee. My name is Raymond Scalettar. I am a physician in the practice of internal medicine and rheumatology in Washington, D.C. I am also a member of the Board of Trustees of the American Medical Association.

With me today is Janet Horan of the AMA's Division of Federal Legislation.

The AMA is pleased to testify on this very important issue today. Two years ago we presented testimony citing the benefits of accurate office clinical laboratory testing for both patients and physicians through improved access, diagnostic timeliness, and patient convenience. At that time we supported an expanded Federal role in assuring accurate laboratory testing. We also recognized the need to establish a baseline of feasible and flexible standards as the starting point to assure the quality of laboratory services.

Since passage of CLIA '88 we have made concerted efforts to work with the government toward this end and we support appropriate Federal regulations. However, it is clear that even with the passage of time, we still are not close to having those standards available. We hope that this hearing will be a catalyst to achieving a goal of feasible and flexible clinical laboratory standards.

The AMA is sympathetic to the Health Care Finance Administration's administrative and regulatory burden. Prior to CLIA '88 the Federal Government regulated approximately 12,000 laboratories. Now HCFA is mandated to regulate an additional 300,000 to 600,000 facilities. This task is enormous and extremely complex.

To aid HCFA in developing standards the AMA was among the over 60,000 individuals and entities that drafted a response to HCFA's proposed regulations. We believe that our comments represent a balanced approach to assure the quality of laboratory tests. We believe that the AMA proposal should be seriously considered as a basis to facilitate the implementation of CLIA '88.

The AMA is seriously concerned that implementation of the proposed regulations will occur without consideration of the testing sites and such an approach would severely jeopardize patient access to affordable quality laboratory and medical services. We believe that the site of the laboratory test can and must be considered for variable controls in the regulatory scheme.

The legislative history of CLIA '88 bears this out. These proposed regulations will set standards for sites ranging from a solo physician's rural practice to major metropolitan group practices, thus the testing site must be considered in any regulatory scheme if 600,000 entities are to be regulated effectively.

Again, as we have said repeatedly, physicians try to provide a wide range of quality testing for their patients. As such we are sincerely interested in a system for the orderly promulgation of the regulations to implement this statute and offer three specific suggestions to facilitate implementation of CLIA '88.

We believe that the creation of a technical advisory committee granting deemed status for accrediting organizations and the creation of a new Level A category of testing will greatly facilitate the implementation of CLIA '88.

First, the proposed regulation suggests the creation of a technical advisory committee to continually review this regulation and make recommendations for changes. We strongly support the establishment of this committee and call for its implementation now to assist in refining CLIA '88 and to have a greater role and more input in the regulatory development process. This will assure that the final regulations will be sufficiently flexible in establishing testing categories to recognize current and changing testing technology.

Since CLIA '88 specifically is designed to regulate the physician in office laboratory, the AMA is convinced that the establishment of an advisory committee with practicing physician involvement is vital to the success of the implementation of CLIA '88.

The AMA is willing to act as a liaison between HCFA and the various medical specialty societies and offers to assist HCFA in establishing this committee immediately.

Second, deemed status must be granted to organizations currently accrediting laboratories. The AMA has consistently supported voluntary accreditation of physician in office laboratory testing and has both supported and funded the Commission on Office Laboratory Assessment, COLA, which is designed to provide voluntary accreditation and education programs for physician in office laboratories.

For this reason we urge HCFA to give such deemed status to the Commission on Office Laboratory Assessment, the College of American Pathology, and the Joint Commission on Accreditation of

Health Care Organizations as well as others currently engaged in accrediting laboratories. We believe that this deemed status will allow more efficient and expeditious HCFA monitoring of the quality of laboratory services.

Third, the creation of the AMA new Level A testing category will facilitate the appropriate level of regulation for physicians performing in office testing. Patient access to needed laboratory tests must not be unduly restrictive. Burdens on patients, including delays in diagnosing treatment, increased travel time, and repeat office visits, are not justifiable, particularly when the goals of the law can be achieved without such burdensome results.

Our standards for Level A are described in our written statement.

The AMA believes that this proposal more clearly reflects the goals of CLIA '88 and will successfully increase the number of physicians participating in proficiency testing programs for their laboratories.

Five studies were mandated by CLIA '88 to be completed by May 1st, 1990. The AMA is concerned that without these studies the regulations are likely to be unresponsive to reality, unnecessarily burdensome, ineffective, and will not measurably increase the quality of tests. The AMA believes that these studies, already overdue, along with a routinely required regulatory impact study, would provide a sound basis for redrafting the regulations. The AMA strongly believes that a regulatory impact study is so important that we as part of the coalition with the Health Industry Manufacturers Association, the Health Industry Distributors Association, and the American Hospital Association have undertaken a study which will be completed in October, 1991. The focus of the impact study will be to quantify the regulatory impact of CLIA '88 in the context of a cost benefit analysis.

For example, the study will capture the anticipated effects on the type, location, and volume of tests as well as the number and variety of test sites. Estimates of the dollar value of these effects will be presented.

In conclusion, we believe that the three modifications we have suggested to the proposed regulation along with the impact study will allow HCFA to implement CLIA '88 realistically without jeopardizing patient access to needed and affordable laboratory services. We believe that our proposal is a workable, reasonable method to achieve the goals of CLIA '88.

Because the proposed regulations must be substantially rewritten we request the publication of a second proposed regulation subject to public comment prior to the establishment of final regulations. While this second review will take time, such a complex regulatory scheme involving so many people and locations needs careful, thoughtful analysis. Views received prior to full implementation could anticipate problems and guide HCFA in establishing the least disruptive application of the regulations.

Once the regulations become final, the AMA will assist in providing information to physicians as well as consumers on CLIA '88. We have several methods of providing information available, such as articles in the Journal of the American Medical Association, American Medical News, the AMA's weekly cable TV program, AMA TV news releases and releases to county, State and specialty medical societies.

We applaud the committee's efforts to assist with the implementation of CLIA '88 and at this time we would be pleased to respond to your questions.

Thank you.

[Testimony resumes on p. 171.]

[The prepared statement of Dr. Scalettar follows. Attachments referred to may be found in subcommittee files.]

STATEMENT
of the
AMERICAN MEDICAL ASSOCIATION
to the
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
U.S. HOUSE OF REPRESENTATIVES

Presented by
Raymond Scalettar, MD

RE: Implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88)

May 2, 1991

Mr. Chairman and Members of the Committee:

The AMA is pleased to testify on this very important issue today. Three years ago, we presented testimony citing the benefits of accurate office clinical laboratory testing for both patients and physicians through improved access, diagnostic timeliness and patient convenience. At that time, we recognized the need to establish a baseline of feasible and flexible standards as the starting point to assure the quality of laboratory services. Since passage of CLIA-88, we have made concerted efforts to work with the government toward this end.

However, it is clear that even with the passage of time we still are not close to having those standards available. We hope that this hearing will be a catalyst to achieving the goal of feasible and flexible clinical laboratory standards.

The AMA is sympathetic to the Health Care Financing Administration's (HCFA) administrative and regulatory burden. Prior to CLIA-88, the federal government regulated approximately 12,000 laboratories. Now, HCFA is mandated to regulate an additional 300,000-600,000 facilities. This task is enormous and extremely complex.

To aid HCFA in developing standards, the AMA was among the over 60,000 individuals and entities that drafted a response (See Appendix I) to HCFA's proposed regulations. We still believe that our comments represent a balanced approach to assure the quality of laboratory tests. We believe that the AMA proposal should be seriously considered as a basis to facilitate the implementation of CLIA-88.

In developing our proposal, the AMA identified a series of principles to guide our position and comments on CLIA-88. We believe these principles also should serve as a guidepost for HCFA in developing standards.

1) Laboratory testing must be performed with the highest possible standards to ensure quality test results. Proficiency testing is a means to assure high quality tests. Proficiency testing and quality control are recommended as continuing educational tools and the cornerstone of laboratory testing.

2) To meet patient care needs and in some instances contain the cost of laboratory testing, a physician must be permitted to have certain laboratory tests performed in his or her office.

3) For immediate patient management, physicians require rapid test results.

4) To avoid burdens on patients, including delays in diagnosis, increased travel time, and repeat office visits, patient access to needed laboratory tests must not be unduly restricted.

5) Physicians, by their training and expertise, are capable of providing laboratory services for patients within their practices.

6) Federal statutes and regulations must not deny a physician the right to practice medicine by establishing unprecedented federal licensure or certification standards.

7) All laboratory testing should be medically indicated.

8) "Deemed" status must be granted to private accreditation agencies which are approved by the Department of Health and Human Services (HHS) for all levels of testing.

9) An active technical advisory committee to continually assess regulations and changing technology in the laboratory field should be strongly supported. This committee should be established immediately to provide for appropriate implementation of the CLIA-88 regulations.

10) Federal regulations must provide sufficient flexibility in test categories to recognize current testing technology.

The AMA believes that these principles are consistent with CLIA-88.

SITE NEUTRALITY

One of the major issues raised by HCFA is whether implementation of the law requires a "site neutral" interpretation. In our view the proposed regulations not only may, but must, consider the site of the laboratory tests in establishing the degree of regulation. Such application would be consistent with the underlying statute. The following statement from the legislative history of CLIA-88 clearly indicates site or type of laboratory must be considered:

> The Committee recognizes that there is a great diversity among laboratories, particularly those associated with physicians' offices, in the scope, nature, and level of sophistication of the testing being performed. A single set of standards, applicable to all such laboratories, would likely be unnecessarily onerous for some and inadequately rigorous for others. Consequently, the Committee has accorded the Secretary, in each of the elements, flexibility to tailor the standards to the needs of the particular type of laboratory in question.

Therefore, the site of the laboratory tests can and must be considered for variable controls in the regulatory scheme.

The AMA is seriously concerned that hasty implementation of the proposed regulations will occur without consideration of the testing sites, and this will severely jeopardize patient access to affordable, quality laboratory services. The magnitude of the effects of the regulation is self-evident. The AMA's Fall 1989 Socioeconomic Monitoring System survey of non-federal patient care physicians (excluding residents) found that almost 43% operated in-office clinical laboratories that will be newly regulated under CLIA-88. This is only a partial indication of the total magnitude of these proposed regulations that will set standards for sites ranging from a solo physician's rural practice to a major metropolitan group practice. Thus, the testing site must be considered in any regulatory scheme if upward to 600,000 entities are to be regulated effectively.

EFFECTIVE LABORATORY STANDARDS

Again, as we have said repeatedly, physicians by and large provide a wide range of quality testing for their patients. However, any level of inaccurate tests is too high. As such we are sincerely interested in assisting with the orderly promulgation of the regulations to implement this statute. We believe that creation of a Technical Advisory Committee, granting of "deemed" status for accreditating organizations, and the creation of a new "Level A" category of testing will greatly facilitate the implementation of CLIA-88.

Technical Advisory Committee

The proposed regulation suggests a Technical Advisory Committee to continually review this regulation and make recommendations for changes. We strongly support the establishment of this Committee immediately to assist in implementing these CLIA-88 regulations. Furthermore, the AMA strongly recommends that such a Committee should have a greater role and more input in regulatory development and implementation as a means to assure that the actual regulations will be sufficiently flexible in establishing testing categories to recognize current and changing testing technology. Furthermore, a coordinating effort among the Committee, HHS, the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) should be established to avoid duplicate efforts when evaluating new laboratory technology. Such cooperation is vital to prevent duplication of efforts through multiple, redundant approval processes. (See Appendix I for a more detailed discussion of this Committee.)

Because CLIA-88 is designed specifically to regulate the physician in-office laboratory, the AMA is convinced that the establishment of an Advisory Committee with practicing physician involvement is vital to the success of the implementation of the Amendments. The AMA is willing to act as a liaison between HCFA and the various medical specialty societies and offers to assist HCFA in establishing this Advisory Committee immediately.

Voluntary Accreditation

The AMA consistently has supported voluntary accreditation of physician in-office laboratory testing. The AMA has both supported and funded the Commission on Office Laboratory Assessment (COLA), which is designed to provide voluntary accreditation and education programs for physician office laboratories.* Activity to initiate COLA as a private sector guarantor of quality in-office laboratories began well before passage of CLIA-88.

Unfortunately, the passage of CLIA-88 may actually have inhibited activities involving such voluntary accreditation programs. Physicians naturally have proceeded cautiously in participating in accreditation programs pending the implementation of CLIA-88. Furthermore, several states have indicated an interest in regulating laboratories to protect their citizens but also have been reluctant to enact state legislation due to the uncertainty of pending federal regulations. To enroll in or establish voluntary programs in conflict with federal standards would be counter-productive. Thus, we believe that more involvement in voluntary programs will occur once the federal regulations have become final.

---

*See Appendix II for a discussion of COLA performance measures.

We support the proposed element of the regulations to provide for a laboratory to receive its certificate through accreditation by private, non-profit, HHS approved accrediting agencies. Such accreditation would be an effective method to begin implementation of CLIA-88. We urge HCFA to give such "deemed" status to the Commission on Office Laboratory Assessment (COLA), the College of American Pathologists (CAP), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as others currently engaged in accrediting laboratories. We believe that this "deemed" status will allow more efficient and expeditious HCFA monitoring of the quality of laboratory services. We believe that, wherever possible, the proficiency testing and quality control standards of these organizations should be incorporated into final regulations. Finally, once regulations become final, a phase-in period will be needed to allow these organizations time to modify their standards, if necessary, for any inconsistencies with the federal requirements.

Phase-In to Full Regulation

Patient access to needed laboratory tests must not be unduly restricted. Burdens on patients, including delays in diagnosis and treatment, increased travel time, and repeat office visits are not justifiable -- particularly when the goals of the law can be achieved without such burdensome results. We believe that the phase-in period provided by the provisional certificate, as set forth in the proposed regulations, is appropriate to provide adequate patient access and time for testing facilities to comply with regulations.

However, we believe that to proceed to collect fees and issue the provisional certificate prior to final regulations and without statutory authority violates the Administrative Procedure Act and the Due Process Clause of the Fifth Amendment of the United States Constitution. For a provisional certificate to have any meaning it must vouch for an established standard. Absent such a standard, we cannot support efforts to issue a certificate that gives just the appearance of having met a quality standard. Perhaps, a registration of testing sites, at this time, might be the most appropriate course of action. Mr. Chairman, the AMA appeciates your assistance in attempting to resolve this issue.

According to the AMA Socioeconomic Monitoring System Autumn 1990 survey, approximately 53% of the physicians who provided in-office laboratory testing participated in a proficiency testing (PT) program. (See Appendix III for details of this survey.) Thus, time will be needed to allow the 47% of the physicians doing laboratory testing but not participating in PT to enroll in proficiency testing programs. Time also will be needed to allow the entities providing laboratories with proficiency testing programs to acquire the capacity to increase their test menus to accommodate these physicians.

ADDITIONAL LABORATORY TESTING LEVEL

In our comments to HCFA, the AMA proposed the creation of a new "Level A" testing category to faciliate the appropriate level of regulation for physician's performing in-office testing. As you know, HCFA proposes a waiver category (with little or no regulation) and Levels

I and II. Our proposal calls for a category more tailored to physicians' offices. This "Level A" will require physicians who are not now involved in a PT program to participate in such programs.

Standards for "Level A" would be as follows:

- Successful participation in a proficiency testing program is required.
- Quality controls and Commission on Office Laboratory Assessment (COLA) or other accreditation are strongly encouraged but not required.
- Tests performed are consistent with the physician's specialty, training or experience.
- Tests are physician interpreted with no other personnel involved except under the physician's on-site supervision.
- Tests are for the physician's own patients.
- Laboratory would be subjected to on-site inspection if suspected of being out of compliance with the certificate.

The AMA believes that this proposal more clearly reflects the appropriate desire of Congress to focus on outcomes. This proposal, coupled with the encouragement of voluntary accreditation such as COLA, will successfully improve clinical testing outcomes by increasing the number of physicians participating in PT programs for their laboratory testing and effectively achieve the goals of CLIA-88. (This proposal is more fully discussed in our regulatory comments, Appendix I.)

CLIA-88 STUDIES

Five studies were mandated by CLIA-88, to be completed by May 1, 1990. The AMA is concerned that without such studies, the regulations are likely to be unresponsive to reality, unnecessarily burdensome, ineffective and will not measurably increase the quality of tests. These important mandated studies concern: (1) the validity, reliability, and accuracy of proficiency-testing; (2) the correlation between personnel standards and the accuracy of test results; (3) the correlation between quality control programs and accuracy of tests; (4) the extent and nature of the problems caused by inaccurate tests; and (5) the effect of test errors on the clinical testing process. The AMA believes that these studies, already overdue, along with the routinely required regulatory impact study, would provide a sound basis for redrafting the regulations.

The AMA so strongly believes that a regulatory impact study is so important, that we, as part of a coalition with the Health Industry Manufacturers Association, the Health Industry Distributors Association, and the American Hospital Association, have undertaken a study which will be completed in October, 1991.

The focus of the impact study will be to quantify the regulatory impact of CLIA-88 in the context of a cost-benefit analysis. For example, the study will capture the anticipated effects on the type, location, and volume of tests, as well as the number and variety of test sites. Estimates of the dollar value of these effects will be presented. The study also will focus on the value and extent of both "centralized" and "decentralized" (alternate site) laboratory testing and the potential effects of the proposed regulations. Efforts will be made to measure or infer the effects the legislation will have on the quality of and access to care.

Those sectors of the health care system affected by CLIA-88 that will be included in the full impact analysis are:

- Alternate sites - this includes physician office laboratories (POLs), ambulatory care centers, community and rural health clinics, and staff model HMO's.
- Hospitals - all testing sites.
- Reference Laboratories - laboratories that provide commercial or specialty testing services to health care providers.

Other sectors of the health care system will be analyzed on a more qualitative level. These include:

- Industry - manufacturers and distributors of laboratory testing equipment and supplies.
- Federal and state governments - measuring the cost of oversight by federal and local agencies.
- The public - the impact the proposed regulations are likely to have on quality and access to care.

The Coalition has established a panel of independent experts with established reputations in diverse fields to assist with the study. This panel will be responsible for reviewing and providing advice at each stage of the project, and thus will help to ensure that the study is technically sound. The Coalition hopes that these results will be helpful in establishing final regulations. The Coalition will be happy to share the results of this study with the Committee.

CONCLUSION

We believe that the modifications we have suggested to the proposed regulations will allow HCFA to implement CLIA-88 realistically and without jeopardizing patient access to needed and affordable laboratory services. The AMA proposal for a new "Level A" is feasible and would eliminate many of the harsh effects of the proposed regulations. Our proposal is a workable, reasonable method to achieve the goals of CLIA-88.

We request that the publication of a second proposed regulation be subject to public comment prior to the establishment of final regulations. Such a complex regulatory scheme needs careful, thoughtful analysis. Views received prior to full implementation could anticipate problems and guide HCFA in establishing a more effective and the least disruptive application of the regulations.

Once the regulations become final, the AMA is prepared to assist in providing information to physicians as well as consumers on implementation of CLIA-88. We have several methods of providing information available, such as articles in JAMA and AM News, the AMA's weekly cable TV program, AMA TV news releases, and releases to county, state and specialty medical societies. In addition, the AMA is exploring the possibility of publishing a consumer magazine on health issues, which certainly would include consumer information on laboratory testing.

We applaud the Committee's efforts to assist with the implementation of CLIA-88.

At this time we will be pleased to respond to your questions.

5938p

Mr. WYDEN. Doctor, thank you and we'll have some questions in a moment and, Madam Recorder, we'll ask that the full statement of the American Medical Association be entered into the record in its entirety.

Mr. Magazine, we welcome you, and again, I'm told that it's going to need to be out of this room earlier than usual, so we'll make your prepared statement a part of the record as well, and if you could highlight some of your major concerns, that would be helpful.

TESTIMONY OF ALAN H. MAGAZINE

Mr. MAGAZINE. Thank you, Mr. Chairman. I am Alan Magazine. I am president of the Health Industry Manufacturers Association. Mr. Allen joins me, not as legal counsel, but because he is the individual overseer in the work on CLIA for our association.

HIMA, as you know, is a national trade association representing approximately 300 manufacturers of medical technology. Its primary role is to represent those manufacturers' interests in legislative and administrative arenas, particularly when changes in regulations have been contemplated.

Included in our membership are the principal U.S. manufacturers of clinical laboratory equipment , diagnostic kits, reagent controls and calibrators. The companies have played a major role in creating the modern clinical laboratory and many of the same companies have developed specialized equipment specifically intended for use in today's alternative testing sites, including physician offices, ambulatory care centers and so on. Their equipment and kits have substantially improved the accuracy and precision of lab tests by standardizing the procedures and reducing human error.

HIMA supports the intent of the Clinical Laboratory Improvement Act of 1988. Our concern is that the regulations implementing the law reflect its mandate to establish standards appropriate for the diversity of the testing sites and the sophistication of today's technology. Responding to the proposed regulations, HIMA members based their comments not only on their knowledge of laboratory science, but also on their vision of how their products, both current and future, can bring diagnostic information directly to the physician and patient.

Laboratory equipment will continue to improve dramatically as it has in the past. These improvements have had three major effects: they have significantly improved the accuracy and precision of test results. They have significantly improved patient access to laboratory tests by making the technology widely available, and they have significantly simplified the performance of virtually all lab tests and reduced the likelihood of human error.

Our comments on the proposed standards regulations issued on May 21, 1990, a copy of which will be submitted for the record, emphasized that the regulation would affect virtually all aspects of laboratory practice, ranging from the traditional reference laboratory to physician office laboratories to public health screening and bedside testing.

We noted that the laboratory equipment industry is currently regulated by the Food and Drug Administration. This Agency regulates all significant aspects of the manufacture and labeling of medical equipment. FDA regulation contains special provisions for in vitro diagnostic devices. They require manufacturers to provide a substantial amount of information in the labeling, including data on all important performance parameters such as the accuracy, precision, sensitivity and specificity of the tests. We suggested that FDA and HCFA establish appropriate and consistent regulations and that those two agencies coordinate their regulatory programs.

Laboratories should not be forced to choose between following manufacturers' instructions which are subject to FDA review, or complying with HCFA requirements. For example, the proposed standard regulation contains technical requirements for calibrators and controls which are obsolete for some current technology.

In our comments, we also noted that we believe that HCFA seriously deviated from Congressional intent by proposing a test classification scheme that does not examine test methodologies. It is our view that classification must be determined through the use of a model that examines test methodologies and characteristics in a systematic, scientifically defensible and equitable fashion.

We proposed such a classification scheme that uses specific criteria to classify facilities, rather than tests. By the complexity of the examinations, procedures or methods performed. We suggested that HCFA should charge the laboratory director for assuring that the staff has the requisite knowledge and skills to produce consistently high quality results for the testing technology used.

Finally, we expressed concern that the proposed regulation may freeze technology and cause manufacturers to abandon new advances because the regulatory hurdles will make it commercially untenable.

Let me just quickly summarize on the issue of training, Mr. Chairman. The companies that make up the Health Industry Manufacturers Association who are involved in the manufacture of diagnostic equipment, laboratory equipment and so on, comprise over 90 percent of the domestic industry.

We did a very quick survey and found that there is extensive training that goes on. Most companies have central training facilities and perform extensive training in the field as well.

Manufacturers thoroughly educate, train and work with the laboratory staff in these training sessions to ensure competency. Many training programs conclude with a certification test to assure that staff will be prepared to run the equipment accurately in the setting for which the equipment is intended. Once the training at a particular site is complete, retraining is available at the request of a medical director or physician, in many cases, at no additional cost.

I understand that the committee has concerns about the marketing practices of some of some of the manufacturers of laboratory equipment. Certainly, the new level of technology reflected in laboratory equipment has led some companies to advance that equipment's convenience features, however, we're not aware of manufacturers who currently oversimplify or deemphasize the expertise required to ensure safe and accurate testing in any setting.

I should note that the Association has not generally involved itself with advertising or marketing activities of our members due to antitrust concerns. The issue of the impact study has been covered by Dr. Scalettar, so I won't go over that.

Let me say in conclusion that I would like to thank the members of this committee for this opportunity. We support the intent of CLIA and are anxious to have rational regulations in place to assure the safety and accuracy of laboratory testing at all sites. Assuring access to quality health care is our highest priority.

Mr. **Wyden**. Mr. Magazine, that's very helpful. We'll have some questions in a moment. Dr. Kroger?

TESTIMONY OF J. STEPHEN KROGER

Mr. **Kroger**. Mr. Chairman and members of the committee, I am Stephen Kroger, Chief Executive Officer of the Commission on Office Laboratory Assessment, a voluntary, non-profit educational and accrediting organization for the physician office laboratory. The acronym for our organization is COLA.

It was conceived by the American Academy of Family Physicians, the American Society of Internal Medicine, the American Medical Association and the College of American Pathologists in 1985, and was incorporated in May of 1988. On July 6, 1988, I presented testimony to the Subcommittee on Health and Environment about the formation of COLA.

I'm pleased to return at this time to provide you with further information. So that there is time for questions, I will summarize the written testimony that we have submitted to the committee.

The COLA accreditation standards and methodology were developed by internists, family physicians and pathologists as a peer review program for office laboratories and are completely consistent with the intent of CLIA '88. The standards require that the physician laboratory director select the proper space, facilities, instrumentation and personnel to provide prompt and accurate reporting of results.

There must be a quality assurance program in place that contains a quality control program, proficiency testing and instrument maintenance program and continuing education. Laboratories are evaluated against these standards using a detailed self-inspection checklist and extensive personnel report forms, successful participation in proficiency testing and problem-oriented onsite inspection of the laboratory facility.

I would like to emphasize that every laboratory participating in the COLA program has its proficiency test results reviewed every quarter by COLA staff. The laboratory director is notified if performance is falling and if there is a risk of losing accreditation.

COLA currently has 1336 laboratories enrolled and accredits laboratories in 49 States and the District of Columbia. Physicians operating these laboratories are family physicians, internists, internal medicine subspecialists, allergists, surgeons and others. Eight hundred and fifteen laboratories have either full or provisional accreditation, 395 are in the process, and 60 laboratories are on probation.

This accounts for 4.2 percent of the enrollment base, and it means that they have failed proficiency testing in two consecutive or two out of the last four challenges, and that they must complete two successful proficiency testing challenges before they are re-accredited. Sixty-four laboratories have withdrawn, often because of expressed concerns and uncertainty regarding the regulations under CLIA '88, and three laboratories have been denied accreditation because they failed to meet COLA standards.

Other program statistics are included with our written statement, but I would like to take a moment to point out that our surveyor has inspected 57 laboratories in the past 15 months and has not found a single instance of laboratory practices that would constitute an immediate danger to patients.

The COLA program was developed with the recognition that there are a large number of office laboratories that would need accreditation. As a result, we have developed a data management system to automate the proficiency testing grading, and we will soon be able to handle approximately 40-50 laboratory applications a day.

We also expect to continue to increase our capacity as need grows, and to soon implement our plan for a national network of laboratory surveyors. COLA is also embarking on an aggressive national and targeted State marketing program to make the benefits of COLA better known to more physicians.

We enjoy the support and cooperation of our sponsor organizations in this effort. Among other things, they are including COLA promotional materials in their proficiency test program mailings, they have provided opportunities for us to present COLA at national, regional and State meetings, and they frequently mention COLA in their newsletters, newspapers and magazines.

Mr. Chairman, you have specifically asked the Commission's position on the proposed regulations for implementing CLIA '88. COLA's founders were already committed to improving the quality of office laboratory testing when they began the groundwork for COLA in 1985, and they since have supported CLIA '88 as appropriate legislation.

As you know, there has been tremendous concern that the proposed regulations of May 21, 1990 will result in the closure of many, if not most office laboratories and will have a significant negative impact on the delivery of timely and cost-effective patient care. This concern was demonstrated by the more than 60,000 written responses to the Health Care Financing Administration.

It is the position of the Board of Directors that COLA's standards and methodologies should be used as a model for appropriate and cost-effective regulation of the office laboratory and that COLA should be a part of the solution to the enormous task of laboratory regulation facing the Nation.

The Commission does not favor unnecessary delay in the development and implementation of fair and enforceable regulations. However, as we stated in our letter to Dr. Wilensky regarding the August 20, 1990 proposed rule for deeming authority, and I quote, "The Commission believes that the Department has a serious obligation to the public to publish the implementing regulations for CLIA '88 in their entirety for additional public comment after consideration of the public comments provided them on the separate notices of proposed rulemaking."

The Commission takes this position because of the interdependence of the several notices implementing CLIA and their complexity which made it extraordinarily difficult to develop a comprehensive view of the impact of these regulations. Comments to one NPRM are frequently predicated on the contents of another, which contents may change under the final rule, and thereby render the commentary to the first proposed rule irrelevant.

In addition, the controversy surrounding the May 21 NPRM is so great that public comment should be solicited on the changes. Mr. Chairman, the Commission is convinced that practicing physicians want to use the best laboratory data they can in treating their patients. To this end, we are firmly committed to using the COLA program to improve the quality of laboratory testing.

The Commission recognizes the role of regulation in the laboratory industry and is committed to working with this committee and the Health Care Financing Administration to assist in the development of meaningful and implementable rules. We believe that the COLA program provides an operational model from which regulations can be derived for the physician laboratory.

The Commission and sponsoring organizations recognize that there is a great need for a profession-based private accrediting option available to practicing physicians in the post-CLIA regulatory period. We are committed to assisting COLA participants to meet this challenge and will cooperate fully with the Health Care Financing Administration to receive deeming authority under CLIA '88.

In this way, the Commission can provide a voluntary alternative to Federal regulation and can also be part of the solution of the task of implementing CLIA. Thank you.

[Testimony resumes on p. 205.]

[The prepared statement and attachments of Dr. Kroger follow:]

TESTIMONY
OF THE
COMMISSION ON OFFICE LABORATORY ASSESSMENT
ON THE
FEDERAL GOVERNMENT'S IMPLEMENTATION OF
THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE

Mr. Chairman and Members of the Committee:

I am Stephen Kroger, M.D., Chief Executive Officer of the Commission on Office Laboratory Assessment, a voluntary non-profit accrediting organization for the physician office laboratory founded by the American Academy of Family Physicians, the American Society of Internal Medicine, the American Medical Association and the College of American Pathologists. The acronym for our organization is "COLA."

On July 6, 1988, I presented testimony to the Subcommittee on Health and Environment about the formation of COLA. I am pleased to return at this time to provide you with further information about COLA, to share with you the information we have gathered in the past two-and-one-half years of accrediting physician's office laboratories, and to let you know of our strong commitment to improving the quality of testing in these laboratories.

HISTORY

The Commission on Office Laboratory Assessment (COLA) evolved from the College of American Pathologists' Primary Care Practice Committee. In March 1985, the American Society of Internal Medicine (ASIM), The American Academy of Family Physicians (AAFP), the College of American Pathologists (CAP), and the American Medical Association (AMA) met in Chicago to determine the feasibility of establishing a physician office laboratory education and assessment service. AAFP, ASIM, and CAP identified key individuals who were either Board members or experienced in office laboratories from their respective organizations; these COLA representatives, through a consensus-building process, developed the standards and assessment mechanisms for accrediting an office laboratory. Forty laboratories operated by members of AAFP and ASIM cooperated in a pilot project to evaluate these standards and mechanisms and provided valuable information in finalizing the program.

In February 1987, the COLA representatives reviewed the data collected during the pilot project. The meeting participants unanimously endorsed standards for physician office laboratories and agreed upon the necessary elements for an ongoing service. In September 1987, the representatives contracted with the Lauer, Lalley, and Associates Research Consulting Firm in Washington, D.C., to do a market research study of primary care physicians to determine the feasibility of a market for the COLA program. COLA staff also sent draft texts of the various COLA program elements to 50 state health department directors and solicited their comments on the program content.
In April 1988, the COLA representatives petitioned the sponsors to incorporate COLA as an independent non-profit entity and to pledge sufficient funds to implement the program. The AAFP Board of Directors, ASIM Board of Trustees, and the CAP Board of Governors voted to approve COLA's incorporation and each pledged a line of credit for the start-up phase of the new corporation.

COLA's Articles of Incorporation were filed in the State of Illinois on May 17, 1988, with the stated purpose "to establish a voluntary educational and accreditation program to help ensure and upgrade the quality of data produced in physicians' office laboratories and thereby enhance the quality of patient care, and to provide a mechanism for accreditation of such laboratories." Each sponsor elected three members to serve on the nine member COLA Board of Directors; on September 18, 1988, the COLA Board of Directors amended the COLA bylaws to allow the American Medical Association to become the fourth COLA sponsor.

ENVIRONMENT

Physician office laboratories (POLs) are a diverse group of testing sites, with the only common elements being that the laboratory has a physician director and the testing occurs in proximity to outpatient care areas. These areas may be in outpatient clinics associated with larger institutions or community health clinics, or in the office of clinicians seeing out-patients.

These laboratories are used by internists, primary care physicians and most medical specialties including pediatricians, allergists, family physicians, obstetrics-gynecologists, oncologists, dermatologists, and many others, to obtain test results as fast as possible to expedite patient care. The proximity to patient care areas and the testing methods used are intended for this purpose.

Internists, for example, use results in the following ways: prothrombin time to monitor anticoagulant therapy; digoxin and theophylline drug levels to monitor therapeutic effects and drug toxicity in cardiac and asthmatic patients; blood sugars and fructosamine to monitor diabetics' control; kidney function tests to determine the presence of kidney disease, and to establish baseline function prior to and during treatment with certain drugs;

liver function for the same reasons; thyroid tests to diagnose hypothyroidism or to monitor thyroid therapy; WBC differential counts to assist in diagnosing infections, or blood disorders, or to monitor chemotherapy; joint fluid examination to diagnose gout or other acute arthritis; pharyngeal and genitourinary cultures to diagnose infection prior to treatment. This testing is as much a part of the practice of medicine as the stethoscope or blood pressure cuff and has become integral to modern diagnosis and treatment.

The testing menu of any given POL is determined by the practice specialty, the number of physicians served, the ease of performance of the tests, and the presence of trained personnel. A pulmonary specialist may want immediate blood gases and have no need for pregnancy tests whereas the pediatrician will want rapid strep tests and urine cultures. Other examples abound.

Technology has dramatically changed the POL in the past 10 years. Tests previously thought possible only in large reference labs can now be performed promptly, accurately, and with ease in the outpatient lab. This is especially true of chemistry analyzers with prepackaged reagents and of hematology instruments that can do an entire hematology profile, including differential counts, without personnel intervention beyond introducing the specimen into the instrument. Kits, packaged with their own controls, have made a variety of test results immediately available, including pregnancy tests and rapid strep tests.

Personnel in POLs vary from on-the-job trainees to medical technologists to the physician. In general, the more complex the laboratory, the greater their formal training. For example, laboratories operating large analyzers capable of processing hundreds of tests a day, or laboratories performing complicated bacteriology tests (blood cultures, anaerobic cultures, detailed identification, etc) will employ medical technologists.

An in-house random survey of 1,500 ASIM and 1,500 AAFP members in 1986 gives some idea of the office laboratory environment. Nearly one-half of those surveyed responded. Forty five percent were in solo practice, 40% in group practices of 5 or less, and 14% were in large groups. The average number of lab employees was 3.9 for AAFP and 2.7 for ASIM. Medical Technologists (baccalaureate degree) were employed by 23% of AAFP and 31% of ASIM labs. An additional 20% of AAFP and 24% of ASIM members employed Medical Laboratory Technicians, and 9% and 11% respectively employed clinical laboratory assistants. Trained laboratory personnel, then, accounted for 52% of AAFP and 66% of ASIM lab employees. Physicians reported that they performed some testing in 59% of AAFP and 45% of ASIM labs.

Personnel not formally trained in laboratory medicine also do significant testing. In the same survey, 35% of AAFP and 20% of ASIM members used registered nurses; 29% and 13% respectively used licensed practical nurses; 19% and 15% respectively used on-the-job trainees. These personnel may be the only ones performing tests in smaller labs, but clearly, many labs employ at least one laboratory-trained person with lesser trained individuals performing some tests.

COLA STANDARDS

The Commission on Office Laboratory Assessment has three standards for the office laboratory. They are:

1. Physician office laboratories shall have sufficient space, equipment, facilities and supplies for the performance of the required volume of work with accuracy, precision, efficiency and safety and provide prompt, reliable reporting of results.

2. Physician(s) who direct the laboratory shall be responsible for insuring that there are sufficient personnel with adequate training to conduct the work of the laboratory.

3. Each laboratory shall have a quality assurance program designed to assure the reliability and medical usefulness of the laboratory data which contains the following components:

    A. Selection of test methods appropriate to the needs of those served by the laboratory and within the technical capabilities of the facility.

    B. A quality control program which monitors the precision of laboratory performance.

    C. A proficiency testing program.

    D. An instrument maintenance program.

    E. A continuing education program for laboratory staff.

    F. Reasonable documentation of laboratory functions.

THE COLA PROGRAM

Based on an understanding of this environment and recognizing that any quality assurance program must be cost-effective, the COLA accreditation program uses four key elements to assess the activities and quality of performance of the office laboratory: the self-inspection survey, personnel requirements, proficiency testing, and on-site inspection.

I. Self-Inspection Survey

An extensive survey of all laboratory operations is completed by the physician laboratory director and the laboratory staff. This survey addresses all areas of laboratory operations including procedure manuals, personnel, record keeping, laboratory safety, instrumentation, and quality control, and has eight sections devoted to technical questions about laboratory testing, (eg., urinalysis and manual hematology.) These questions reflect requirements established by the Board of Directors for accreditation and are divided into "major" and "minor" criteria. The laboratory must meet all 39 major criteria.

All reported information is cross-referenced by COLA staff to identify inconsistencies in reporting and to determine whether the laboratory is in compliance with COLA requirements. When deficiencies or discrepancies are identified, a letter is sent to the laboratory director giving specific instructions on what must be done to correct the deficiency or requesting clarification of a discrepancy. The response to this letter is evaluated by COLA staff and a decision is made whether to ask for further information (if the answers received are unsatisfactory), or to recommend accreditation to the Board of Directors.

II. Personnel Requirements

Each laboratory worker completes an extensive questionnaire which details the worker's personnel training and the specific tests performed by that employee. The laboratory director is required to review this form and to attest that the workers are adequately trained to perform these procedures. Responses from personnel are cross-checked with the laboratory self-inspection survey to identify discrepancies in the test menu or equipment.

The Board of Directors has taken under review a requirement that the laboratory director observe all new employees performing tests on specimens that have a known value. In this way the director can evaluate their ability to operate the instrument and accurately report test results.

III. Proficiency Testing

COLA requires laboratories to be enrolled in a proficiency testing program that meets COLA standards and to pass at least three of four quarters of testing with an overall grade of 80%. COLA personnel monitor every laboratory's proficiency testing performance for each analyte each quarter and notify the laboratory director if there are performance problems in advance of a change in accreditation status. This gives the laboratory an opportunity to correct problems without losing accreditation.

The COLA Board has developed fixed grading criteria for proficiency testing for 39 analytes appropriate to the office laboratory. These fixed limits were developed by determining the clinically relevant acceptable ranges for an analyte and the types of instrumentation available in the office laboratory rather than using limits derived from the performance of state-of-the-art instrumentation found in large laboratories.

Laboratories performing poorly in proficiency testing over time will be identified, and the causes of poor performance, whether they be inappropriately trained personnel, inadequate instrumentation, lack of quality control procedures, or others, will be corrected or the laboratory is dis-accredited.

IV. On-Site Inspection

On-site inspections are necessary to determine a laboratory's compliance with COLA standards and accreditation requirements. COLA recognized early in its development, however, that biennial inspection is not a cost-effective way of evaluating the very large number of office laboratories. The Board believes that the COLA self-assessment mechanism coupled with an ongoing outcome measure (proficiency testing) is the best way of controlling the cost of accreditation to physicians and their patients while still providing assurance that laboratories meet accreditation requirements.

COLA uses on-site inspections several ways:

1. to provide the program with an internal control that assures the Board of Directors that self-inspected laboratories do, in fact, meet COLA standards;

2. targeted inspections directed toward laboratories with recognized performance problems (COLA probationary laboratories);

3. as required by state or Federal statute; and

4. whenever the Board of Directors feels uncertain that a laboratory is meeting COLA's requirements.

Types of Accreditation

A laboratory that meets all COLA criteria, including successful completion of proficiency testing, is given **full accreditation.** Should a laboratory not have been previously enrolled in proficiency testing but all other COLA requirements are in order, the laboratory is given **provisional accreditation.** Should the laboratory later fail to achieve 80% correct results in all analytes for three out of four quarters of testing, it is placed in a **probationary** status;

it must correct inappropriate laboratory procedures and pass the next two quarters of proficiency testing or lose its accreditation. A probationary laboratory must also pass inspection by a COLA inspector prior to re-instatement. Laboratories that fail to meet COLA requirements are **denied accreditation**. Currently, laboratories are accredited for two years, subject to continued compliance with COLA requirements.

Computerization

The accreditation process used by COLA is data intensive. For some time, the Commission has been involved with the design and implementation of a data management system that will automate a considerable part of the routine evaluation of a laboratory, freeing up the technical staff to deal with exceptions and anomalies. Forms designed for optical scanning, automated "cross checks" of the internal consistency in the reports from a laboratory, direct data transfers from proficiency testing programs to the COLA computer system, automatic grading of this data using COLA proficiency testing grading criteria, and automatic customized written communications are among the efficiencies developed in computerization of the program.

Capacity

COLA recognizes that there are large numbers of office laboratories requiring accreditation, and continues to develop the capacity to provide its services to these laboratories. When our current automated processing system is fully operational in September, 1991, it is anticipated that the COLA staff will be able to handle between forty and fifty applications a day. We expect to continue to build capacity into this system over the next several years as the need for COLA's services grows, and expect to be able to handle twice that many applications in the next few years. In addition, the Commission is currently planning for a national network of on-site surveyors who will be hired as the need for site surveys grows.

Educational Offerings

The Commission is committed to providing educational tools to physicians and their laboratory workers. Participants have access to COLA's trained technical staff who are able to answer questions about instrumentation, record keeping, quality assurance, and a host of other topics important to this setting. COLA Laboratory Guides, which address such topics as how to write a procedure manual and how to collect specimens, are available. COLA inspectors use these Guides at the time of inspection to provide more information to laboratory workers when deficiencies are noted.

COLA staff monitor all proficiency testing results in all laboratories on a quarterly basis for purposes of determining compliance with COLA proficiency testing requirements. When staff note incipient problems, the laboratory is notified by letter, perhaps with suggestions, to assist the lab in correcting these problems. This system provides an early-warning device, notifying the laboratory to correct problems before accreditation status is imperiled.

The COLA Update is a newsletter published three times a year (soon to be quarterly) that provides current information on laboratory regulations, pertinent literature reviews, a regular "spotlight" on a successful COLA lab, and other timely information.

COLA is currently developing the COLA Guide to Quality Assurance, which will provide in-depth information about an office laboratory quality assurance program and contains forms to assist in the record-keeping tasks necessary to document laboratory actions.

Promotional Efforts

Improvement of laboratory testing through COLA will occur only when the organization is widely known and recognized as a major benefit to physicians operating laboratories. COLA has developed an extensive marketing program to bring the benefits of the Commission to physicians throughout the country. Both a national and a targeted-state approach are being implemented to increase the awareness of COLA to physicians, professional organizations, laboratory consultants, insurance carriers, and state regulatory personnel. Focused advertising, speaking before professional audiences, endorsement by national and state medical societies and laboratory organizations are among the efforts currently underway to encourage physicians to participate and to make laboratory workers more aware of COLA.

We are working with our sponsor organizations to further increase the awareness of physicians about quality laboratory testing. For example, COLA promotional materials will be included in mailings of the proficiency testing programs operated by sponsor organizations (AAFP's AAFP-PT, ASIM's MLE Program, CAP's Excel program). COLA has been featured on programs at state, regional, and national meetings of the sponsors; the Commission has been mentioned repeatedly in organizational newsletters; the College of American Pathologists has promoted COLA in conjunction with several regional seminars on the role of pathology in consulting with office laboratory directors. More recently, the College has developed a program of printed materials and 35 mm slides about the office laboratory, which features COLA as the appropriate accrediting body for office laboratories.

PROGRAM STATISTICS

General

Attached to this report **[See Appendix A]** are statistics derived from the first two years of operation of the Commission. One should be aware that some of these numbers are "soft" because of changes in the way the data have been gathered and recorded as the organization has gained experience and has moved from a paper system to an electronic one. In addition, because the laboratories voluntarily enrolled in COLA and are motivated to achieve accreditation, they do not necessarily represent the average population of office laboratories.

COLA currently carries 1,336 laboratories in its active file, and has laboratories in 49 states and the District of Columbia. In two states where office laboratory consultants have recommended COLA, the enrollment is substantially larger (OK, MN). **[See chart 1]** The current accreditation status of these laboratories is as follows **[See chart 3]**:

Full Accreditation	280 laboratories
Provisional Accreditation	535
Pending (in process)	395
Probation	60
Denied	3
Closed (Withdrawn)	64

The largest number of laboratories enrolled is operated by solo practitioners and small physician groups; a number of larger group practices are also represented. Family practice, internal medicine, internal medicine sub-specialties, pediatrics and obstetrics-gynecology are all represented. **[See charts 4 and 5]**

Personnel

COLA's data on the training of office laboratory workers is not complete. The questions asked and the method of retrieving personnel data changed in February, 1991, when it was apparent that the Commission was not getting the information needed to track this variable. The preliminary data presented here represents information on 233 laboratories and may not be reflective of the entire population of COLA laboratories; it is similar to the data obtained by the ASIM/AAFP office laboratory survey in 1986 that was presented earlier, however, and shows that more than 2/3 of POLs use workers with at least one year of formal laboratory training. **[See chart 6]**

On-Site Inspection

The findings of on-site inspections are helpful in understanding the strengths and weaknesses of the POL environment. Fifty-seven laboratories have been inspected in 18 states during the 15 months the program has been operative. Of these, 9 inspections have been for removal of probationary status and 48 have been verification inspections. The COLA inspector has not found a single instance of laboratory practices that constitutes an immediate danger to patients, and in fact, all inspected laboratories were in substantial compliance with all COLA requirements.

Chart 7 shows the rate of non-compliance with COLA major criteria found at inspection. Although all laboratories had a procedure manual, the single most common problem was failure to include all tests performed. Since this is a problem for laboratories of all sizes, it is remarkable that 41 laboratories had "perfect" procedure manuals.

The second most common problem is major criterion #102: "Are there criteria for a review of blood cell smears by the physician laboratory director." This type of failure gives the COLA inspector an opportunity to provide information to the director about the reasons COLA expects him/her to review blood smears. The result has been increased cooperation between the director and his lab personnel, and on one occasion, the hiring of a laboratory consultant to provide this service.

Probation Laboratories

At this time, 60 laboratories have been placed on probation because of proficiency testing (PT) failures. This represents 4.2% of the active laboratories and has been consistent over the last several months. **[See chart 8]** The causes of probation are fertile areas of study, since consistent failure of proficiency testing represents a failure of the testing system and could represent a risk to patients. All nine laboratories that have been inspected for removal of probationary status have passed inspection. The high rate of PT failures in microbiology (47% of probation laboratories) is due to artifacts of the PT methodology itself, the inadequacy of certain test methods used for identifying bacteria, and the training of personnel.

We believe that a major contribution to quality testing has been made in these laboratories since they have either stopped testing in microbiology or have changed methods so that the results are more accurate.

It is worth noting here that the types of bacteria sent to laboratories for identification are seldom seen in the POL environment and are more appropriate for specialized microbiology laboratories. This problem will increase dramatically if the CLIA Proposed Rules for Microbiology PT specimen selection are required in the office setting.

Similar progress has been seen in hematology, the discipline with the second largest cause of failures in PT (37% of probation laboratories). The reasons for failure are the same as for microbiology: artifacts of PT testing, instrumentation, and personnel.

It is illustrative of the current trend in chemistry instrumentation that so few laboratories consistently fail chemistry PT (13% of probation laboratories).

As laboratories continue to participate in the accreditation program and their strengths and weaknesses become apparent, physician directors will take action to improve their laboratories. This type of action meets the stated goals of the Commission and validates its methodology for improvement of performance through peer review. As the COLA data base is further developed, the Board of Directors plans to publish its findings in peer-reviewed medical journals.

CLIA 88

The Commission was conceived and in development before the debates began that led to the Clinical Laboratories Improvement Amendments of 1988 (CLIA 88). COLA's founders, the American Academy of Family Physicians, the American Society of Internal Medicine, the American Medical Association, and the College of American Pathologists were already committed to improving the quality of office laboratory testing; and they supported CLIA 88 as appropriate legislation. There has been tremendous concern, however, that the proposed regulations of May 21, 1990, will result in the closure of many, if not most, office laboratories and will have a significant negative impact on the delivery of timely and cost-effective patient care. This concern was demonstrated by the more than 59,000 written responses to the Health Care Financing Administration about the Proposed Rule.

It is the position of the Board of Directors of the Commission on Office Laboratory Assessment that the Commission should be seen as a template for appropriate regulation in the office laboratory setting.

COLA standards have been developed through a peer review process with representation from family practice, internal medicine and pathology, and are consistent with the intent of CLIA 88.

The self-inspection methodology used in conjunction with on-site inspection to validate the accuracy of the program and to target problem laboratories is effective and efficient. It provides an immediate mechanism for identifying sub-standard performance and emphasizes the need for accountability and documentation.

The most appropriate person to know what technical level is needed for the laboratory is the physician laboratory director. COLA holds the physician laboratory director accountable for the employees he or she hires. COLA's personnel standards are appropriate, since they recognize that a wide range of tests are performed in the office laboratory but that baccalaureate-level technical staff may not be necessary to perform them. Statistics presented earlier support the idea that, in general, physicians operating more complex laboratories already hire personnel with greater formal training.

COLA's requirement for proficiency testing is similar to that in the CLIA 88 Proposed Rule; however, COLA has developed grading criteria that are more appropriate to the office setting. These criteria are driven by clinical utility and the instrumentation available to the office laboratory rather than by state-of-the-art instrumentation found in large laboratories. Although COLA recognizes that proficiency testing is best used as a laboratory quality assurance tool rather than as a regulatory tool, it does provide a way of monitoring performance over time.

It is possible to meet the expectations of CLIA 88, protect the public from potentially harmful laboratory results, and keep office laboratories open by using the COLA approach. Office laboratories have demonstrated that, with some effort, they can meet COLA's quality performance standards and proficiency testing standards on an on-going basis, and that they can do so in a cost-effective way.

The Commission does not favor unnecessary delay in the development and implementation of fair and enforceable regulations. COLA is fully prepared to cooperate with the Health Care Financing Administration in the development of meaningful regulations for the office laboratory.

However, the interdependence of the several Notices of Proposed Rulemaking implementing CLIA 88 and their complexity have made it extraordinarily difficult to develop a comprehensive view of the impact of these regulations. Comments to one NPRM are frequently predicated on the contents of another, which contents may change in the Final Rule, thereby rendering the commentary irrelevant. The COLA position was stated in our letter to HCFA regarding the August 20, 1990 Proposed Rule for deeming authority:

> **"The Commission believes that the Department has a serious obligation to the public to publish the implementing regulations for CLIA 88 in their entirety for additional public comment after consideration of the public comments provided them on the separate Notices of Proposed Rulemaking." [See Appendix C]**

COMMITMENT

The Commission is convinced that practicing physicians want to use the best laboratory data they can in treating their patients. To this end we are firmly committed to improving the quality of laboratory testing in the office setting by providing the physician with the educational tools necessary to develop and maintain a quality laboratory and to use the accreditation program as a national benchmark to measure this quality.

The Commission believes that quality assurance is a dynamic process that must be continuously reviewed and modified based on the changing needs of patient care, laboratory technology, and the need for accountability. The Board of Directors is committed to continuously reviewing the Commission's standards and assessment methods to meet these changing needs. For example, the Board is currently reviewing the laboratory director's accountability to COLA in the methods used in selecting laboratory personnel.

The Commission has committed substantial resources to the development and implementation of a national marketing plan to make physicians aware of the benefits of participating in the accreditation program.

The Commission recognizes the role of regulation in the laboratory industry and is committed to working with this Committee and the Health Care Financing Administration to assist in the development of meaningful and implementable rules. We believe that the COLA program provides an operational model from which regulations can be derived.

The Commission and its sponsoring organizations recognize that there is a great need for a profession-based, private accrediting option available to practicing physicians in the post-CLIA regulatory period. We are committed to assisting COLA participants to meet the regulatory challenges of CLIA- 88 and will fully cooperate with the Health Care Financing Administration to receive deeming authority under CLIA-88 for COLA. In this way, the Commission can provide a voluntary alternative to federal regulation and also be part of the solution to the enormous task of laboratory regulation currently underway.

APPENDIX A

CHART 1

COLA Laboratory Statistics by State

As of 4/21/91

State	Number of Laboratories	Number of Physicians	Number of Laboratory Workers	Average Workers per Laboratory
AK	2	2	13	6.50
AL	35	35	84	2.40
AR	20	50	56	2.80
AZ	8	10	19	2.38
CA	51	65	113	2.22
CO	13	18	44	3.38
CT	8	16	23	2.88
DC	4	10	6	1.50
FL	85	135	166	1.95
GA	35	49	89	2.54
HI	1	2	9	9.00
IA	16	39	80	5.00
ID	1	1	3	3.00
IL	17	29	62	3.65
IN	34	89	103	3.03
KS	13	17	27	2.08
KY	31	45	79	2.55
LA	20	36	58	2.90
MA	21	21	34	1.62
MD	8	10	25	3.13
ME	4	4	12	3.00
MI	42	60	65	1.55
MN	139	382	554	3.99
MO	39	90	149	3.82
MS	21	26	40	1.90
MT	4	56	22	5.50
NC	56	111	235	4.20
ND	3	7	8	2.67
NE	18	68	71	3.94
NH	1	1	4	4.00
NJ	23	45	57	2.48
NM	7	18	19	2.71
NV	5	9	6	1.20
NY	49	84	152	3.10
OH	79	141	224	2.84
OK	105	125	144	1.37
OR	7	18	21	3.00
PA	10	13	20	2.00
RI	4	5	4	1.00
SC	25	58	69	2.76
SD	2	2	3	1.50
TN	34	66	96	2.82
TX	93	167	233	2.51
UT	3	7	18	6.00
VA	91	273	318	3.49
VT	6	19	33	5.50
WA	9	9	31	3.44
WI	9	59	45	5.00
WV	23	45	54	2.35
WY	2	2	2	1.00
Total	1,336	2,649	3,802	2.85

CHART 2

COLA Enrollment
by Discipline

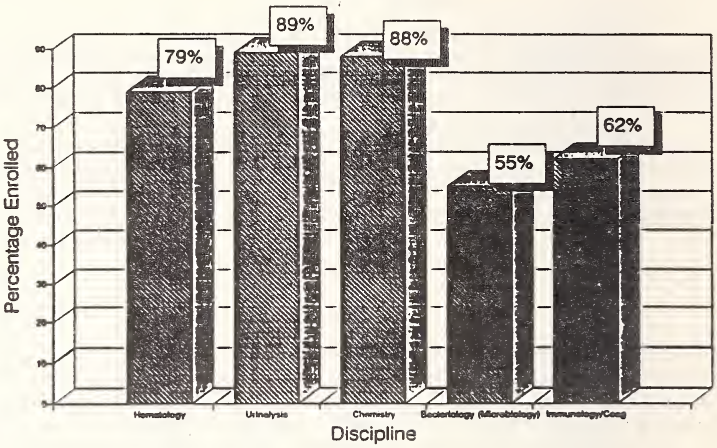


CHART 3

Accreditation Status
as of April 25, 1991

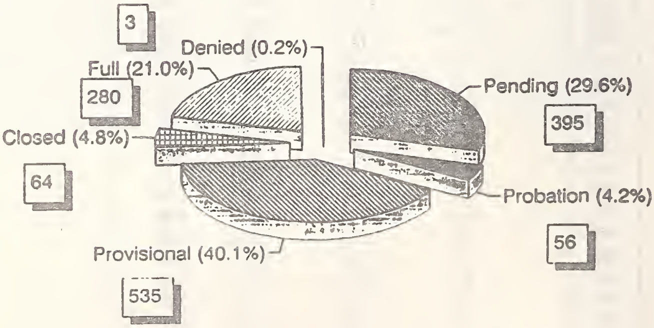


CHART 4

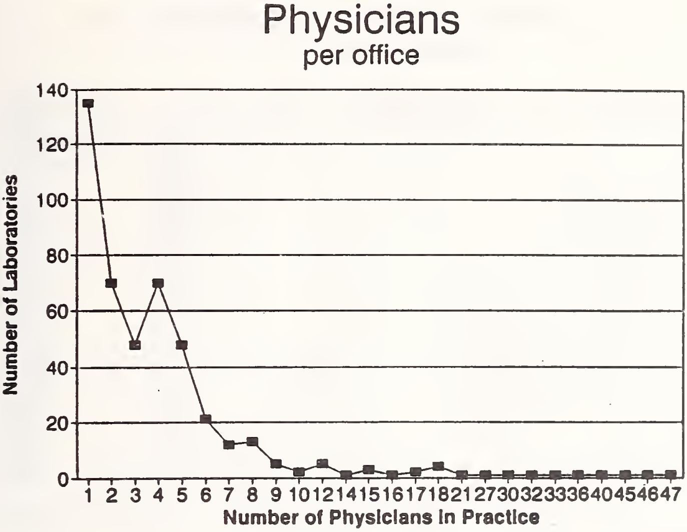


CHART 5

COLA Specialty Statistics
As of 4/21/91

Specialty	Number
Allergy & Immun	19
Cardiovascular	51
ENT	17
Endocrinology	33
Family Practice	215
Gastroenterology	34
Hemat & Oncolo	53
Internal Medicin	175
Nephrology	11
Obstetrics, Gync	44
Pathology	3
Pediatrics	41
Pulmonary Medic	18
Rheumatology	28
Surgery	36
Urology	14
Other	30
Total	424

CHART 6

COLA Personnel Education Statistics

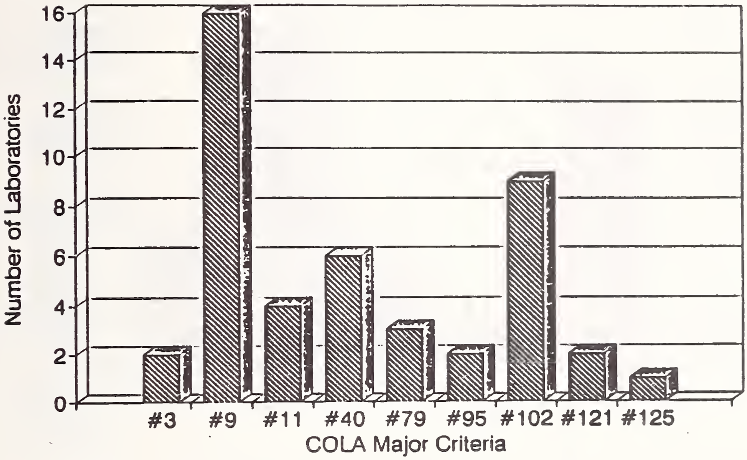
As of 4/21/91

Cat	Descrip	Laboratories		Employees		Avg. Yrs. Experience
		#	%	#	%	
1	MD/DO	25	10.73%	43	11.44%	14.0
2	PhD	2	0.86%	2	0.53%	5.0
3	MS/MA	4	1.72%	4	1.06%	19.0
4	BS/BA	42	18.03%	58	15.43%	11.5
5	Assoc Degree	43	18.45%	64	17.02%	9.8
6	2-year Program	27	11.59%	48	12.77%	12.1
7	1-year Program	48	20.60%	95	25.27%	10.1
8	Manuf Trained	8	3.43%	11	2.93%	9.2
9	OJT	33	14.16%	50	13.30%	9.0
10	No Training	1	0.43%	1	0.27%	0.0
		---------	---------	---------	---------	
		233	100.00	376	100.00	

stats3a

CHART 7

Non-Compliance with COLA Criteria



DOCUMENTED CORRECTIONS REQUIRED FOR THESE QUESTIONS DURING ON SITE INSPECTION

QUESTION #3 - (Do your personnel records include:) A description of duties and specific tests the person is authorized to perform?

QUESTION #9 - Does (the procedures manual) include all tests offered by the laboratory?

QUESTION #11 - (Does the procedures manual contain an) Annual review and approval signature of the physician laboratory director?

QUESTION #40 - Has the laboratory established procedures for the immediate notification of the physician when results of tests exceed predetermined alert value" limits?

QUESTION #79 - Is a urinalysis control product used to check dipsticks at least every two weeks and when a new bottle is opened?

QUESTION #95 - Are all manual hematology tests performed in your laboratory included in the procedures manual?

QUESTION #102 - Are there criteria for a review of the smears (blood cell) by the physician laboratory director?

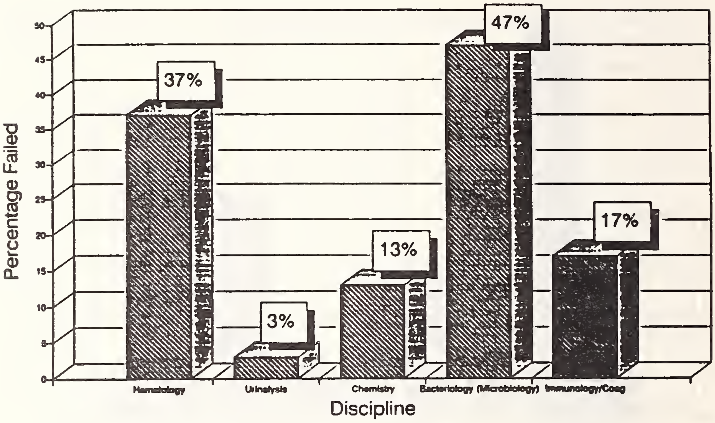
QUESTION #121 - Is a maximal packing test done once a month, that is, is the patient specimen respun to determine if further packing occurs?

QUESTION #125 - Is the ESR tube rack leveled before each use?

CHART 8

Probation Laboratories

PT failure by discipline



APPENDIX B

COLA

Commission on Office Laboratory Assessment

President
Darroll J. Loschen, MD
York, Nebraska
American Academy of
Family Physicians (AAFP)

Secretary
Lonnie R. Bristow, MD
San Pablo, California
American Medical
Association (AMA)

Treasurer
Parry A. Lambird, MD
Oklahoma City, Oklahoma
College of American
Pathologists (CAP)

Member At Large
J. Stephen Kroger, MD
Longmont, Colorado
American Society of
Internal Medicine (ASIM)

Board of Directors
AAFP
Glen Aukarman, MD
Jackson Center, Ohio

Paul Fischer, MD
Augusta, Georgia

AMA
William E. Jacott, MD
North Oaks, Minnesota

Frank B. Walker, MD
Grosse Pointe Farms,
Michigan

ASIM
M. Boyd Shook, MD
Oklahoma City, Oklahoma
Kathleen M. Weaver, MD
Portland, Oregon

CAP
A. Samuel Koenig III, MD
Fort Smith, Arkansas

John H. Rippey, MD
Kansas City, Missouri

Chief Operating Officer
Douglas A. Beigel

August 17, 1990

Gail Wilensky, Ph.D
Health Care Financing Administration
Department of Health and Human Services
Attn: HSQ-176-P
P.O. Box 26676
Baltimore, MD 21207

Dear Dr. Wilensky:

The Commission on Office Laboratory Assessment (COLA) is a non-profit education and accreditation program for the physician office laboratory. As such, we are vitally interested in the federal regulations affecting clinical laboratories, particularly those in the out-patient and office setting.

The Commission shares with Congress and the Department of Health and Human Services the conviction that the public has a right to accurate laboratory test results, although we may differ on what mechanisms should be used to assure that end. The parent organizations of the Commission, the American Academy of Family Practice, the American Society of Internal Medicine, the American Medical Association and the College of American Pathologists, will submit comments to the Department addressing the May 21, 1990 Notice of Proposed Rulemaking implementing CLIA '88.

We wish to submit these comments as part of the public record regarding the May 21 Notice to direct the Department's attention to the cost-effective approach developed by COLA to accredit those 100,000 laboratories in physicians' offices. While we recognize that CLIA '88 is "site neutral," this approach is appropriate as an assessment mechanism for the proposed Level I laboratory, and for many less complex Level II laboratories. By obtaining detailed information regarding a laboratory's personnel, quality assurance and quality control activities, and by monitoring its performance on proficiency testing, we are convinced that we can determine "quality" without a physical inspection of every laboratory.

In the past, we have submitted information to the Health Standards Quality Bureau that describes the COLA program and its underlying philosophy. A summary description of the program [Attachment A] will provide an overview of the program in its current state. Also attached [Attachment B] are program documents that detail specific activities of the accreditation and on-site inspection programs.

Since January of 1989, the Commission has received approximately 1300 applications from office laboratories all over the United States. One hundred fourteen have received full accreditation, 570 have provisional accreditation (meet COLA criteria but have not been enrolled in PT), 24 are on probation and 2 have been denied. The remainder of the laboratories are currently in the process of accreditation. We have completed 24 inspections in 5 States and have 20 inspections scheduled in Washington, Oregon, North Carolina, Texas, and Florida in the next 3 months.

The On-site inspections performed as part of our program validation have been very encouraging. Ten randomly selected laboratories have been inspected for this purpose to date. The only deficiencies identified in these 10 laboratories were paper documentation problems: a test procedure not recorded (8), documentation of personnel training (2), a signature missing (1), alert value missing (1). One laboratory was not performing a maximal packing test to control their hematocrit. The inspector explained the technique and we are confident that the laboratory has instituted the corrective action.

While the number of laboratories inspected for this purpose is small to date, there is a strong suggestion that the methodology developed by COLA is valid and that laboratories accredited by COLA will meet its accreditation requirements. The Commission is convinced that subsequent validation inspections will bear out this conclusion.

The Commission strongly urges the Department to use a certification procedure similar to the COLA model in evaluating Level I laboratories and less-complex Level II laboratories rather than the very expensive approach of biennial on-site inspections. Not only will costs of certification be reduced to the laboratory, the number of inspectors needed to implement the regulations would be substantially reduced as well.

The Commission on Office Laboratory Assessment looks forward to assisting the Department in all possible ways to achieve our common goal of assuring quality laboratory practices in the United States. If we may be of any further assistance, in the development of these regulations, please call us.

Sincerely yours,

Darroll J. Loschen, M.D.
President

Enclosures

Program Description
Bylaws, Page 1
Standards
Standards for Approval of PT programs
Due Process Policy
Application Form
Accreditation Packet
Grading Criteria, Major Criteria
COLA PT Grading Criteria
On-Site Grading Criteria
Policy on Laboratories selected for On-Site Inspection
Section IV, Inspection Process
Letters Sent regarding On-Site
Job Description, Inspector
COLA Fixed Grading Criteria
On-Site Program Mission Statement
Approved PT Programs

ds7724k

APPENDIX C

COLA

Commission on Office Laboratory Assessment

President
Darroll J. Loschen, MD
York, Nebraska
American Academy of
Family Physicians (AAFP)

Secretary
Lonnie R. Bristow, MD
San Pablo, California
American Medical
Association (AMA)

Treasurer
Perry A. Lambird, MD
Oklahoma City, Oklahoma
College of American
Pathologists (CAP)

Member At Large
J. Stephen Kroger, MD
Longmont, Colorado
American Society of
Internal Medicine (ASIM)

Board of Directors
AAFP
Glen Aukerman, MD
Jackson Center, Ohio

Paul Fischer, MD
Augusta, Georgia

AMA
William E. Jacott, MD
North Oaks, Minnesota

Frank B. Walker, MD
Grosse Pointe Farms,
Michigan

ASIM
M. Boyd Shook, MD
Oklahoma City, Oklahoma

Kathleen M. Weaver, MD
Portland, Oregon

CAP
A. Samuel Koenig III, MD
Fort Smith, Arkansas

John H. Rippey, MD
Kansas City, Missouri

Chief Operating Officer
Douglas A. Beigel

October 17, 1990

Gail Wilensky, Ph.D
Administrator
Health Care Financing Administration
Department of Health and Human Services
Attn: HSQ-181-P
P. O. Box 26676
Baltimore, MD 21207

RE: HSQ-181-P

Dear Dr. Wilensky:

The Commission on Office Laboratory Assessment (COLA) is a voluntary non-profit education and accreditation program for the physician office laboratory. The Commission wishes to submit the following comments regarding the Notice of Proposed Rulemaking (NPRM) published August 20, 1990 at 55 Federal Register 33936-46.

APPLICATION AND FEES

This NPRM makes no statement regarding the process by which an accrediting organization applies to the Department of Health and Human Services (DHHS) for deeming authority, the time in which the Department must act upon such application, or the fees charged, if any, for application, validation, review, comparability review, probationary review or appeals.

The Department should publish in the Federal Register and make available for public comment its regulations regarding applications and fees for accrediting/licensing bodies.

EQUIVALENCY OF REQUIREMENTS

You solicit comments regarding how private accrediting organizations and State licensure agencies may demonstrate that certain standards, though different than the federal approach, can be considered equivalent. The Commission does not favor a line-by-line crosswalk approach between the Federal standards and an accrediting organization's standards since such a crosswalk runs counter to the concept of private accreditation, and blurs or eliminates differences between the Federal and private approach to assuring quality laboratory performance. The Clinical Laboratories Improvement Amendments of 1988 (CLIA 88) at Section 353(e)(A)(ii) requires only that the accrediting body's standards be equal to or more stringent than the Federal requirement, not that they be identical.

There must be sufficient flexibility in interpretation of this requirement to permit accrediting bodies to measure laboratory functions in different ways to achieve the same ends required by CLIA 88 and to permit variations of non-essential requirements when compared to Health Care Financing Administration (HCFA) regulations. Flexibility implies a hierarchy of requirements such that the essential requirements of regulation are identified and separated from those that are less essential. This mechanism provides flexiblity between Federal and private/state programs by establishing the areas of required equivalency and yet permits sufficient latitude for different approaches to laboratory quality assurance.

HCFA should provide sufficient flexibility within the regulatory process to provide for differences in accrediting bodies, provided the differences do not materially alter compliance with CLIA 88. HCFA should do this by weighing the various sections of the regulations regarding standards of laboratory performance to establish which standards and conditions are essential to patient safety and which are desirable. It should then require accrediting organizations/licensing agencies to meet all essential requirements and a significant percentage of desirable requirements.

We offer another approach to measuring equivalency:

Instead of comparing items line-by-line, we suggest that HCFA compares the content of the standards against its regulations by specialty. Comparison categories such as Personnel, Specimen collection, Documentation, etc., can be used as may be seen in the attached document which compares the COLA program to the State of Washington requirements for bacteriology (Attachment A).

COMPARABILITY OF THE INSPECTION PROCESS

HCFA offers eight general requirements for comparing the accrediting organization's inspection process with theirs.

493.506(b)(1) requires a determination of the qualifications of the inspection team but offers no indication of what the qualifications shall be. If HCFA develops stringent academic requirements such as found in the NPRM [HSQ-176-P] 20896-20959, the cost and availability of inspectors will be prohibitive to a national inspection effort.

Inspectors should qualify by virtue of their experience in the type and complexity of laboratories they inspect and by the training provided them by the accreditation organization. We believe this statement reflects the intent of Congress [See PHSA 353 (e)(2)(A)(i)].

493.506(b)(2) requires comparability of the inspection process. The Commission believes that it has developed a unique and cost-effective assessment mechanism that is applicable to many laboratory settings but that is different from the traditional regulatory approach. We have submitted information in the past to the Health Quality Standards Bureau that describes the content of the program and its underlying philosophy. In our comments relating to HSQ-176-P we provided further information regarding the program (Attachment B). We are convinced that this is a valid methodology and deserves serious consideration by the Department.

The Commission urges the Department to avoid an overly rigid approach to determining the comparability of its inspection process with that of private accrediting organizations. HCFA should consider using the Commission on Office Laboratory Assessment as a demonstration project to provide a different and cost-effective approach to assessing laboratories, and to determine whether the differences between the Federal regulations and an accreditation organization's requirements materially alter laboratory performance.

493.506(b)(6) requires that HCFA be notified within 30 days of failure of proficiency testing. **Because of duplicative reporting requirements (see below) the Commission believes this requirement should be dropped. If it is not dropped, however, we believe that the 30-day time limit is too short and does not provide the accrediting organization an opportunity to validate the proficiency testing program database or determine extenuating circumstances within the laboratory. It should be sufficient to provide HCFA laboratory-specific**

information on those laboratories that are denied accreditation.

493.506(b)(7,8). This subsection requires HCFA to determine the adequacy of staffing and financial resources of accrediting bodies/state licensing agencies but it is not clear how the Agency plans to accomplish this.

Most accrediting organizations and State health departments do not have a complement of staff and inspectors sufficient to meet the anticipated need under CLIA 88.

HCFA should clarify in the final rule how the determination of adequacy of staffing and finances will be performed.

493.506(c)(4,5). The Proposed Rule HSQ-176-P at 55FR 20896-20959 Section 493.901(b)(4) and 493.903(b) requires proficiency testing programs to submit reports of specific laboratory failures and cumulative reports on an individual laboratory's performance. It is duplicative, costly and unnecessary for an accrediting organization to also submit the same information. Duplicate submission of the same data will result in costly data processing and confusion for the Agency and for the accrediting organization.

The Commission believes that the proficiency testing program should submit a single comprehensive report to HCFA that is coded electronically to identify a laboratory's participation in an accreditation/state licensing agency program.

VALIDATION INSPECTIONS

The Commission on Office Laboratory Assessment agrees with the Department that some measure of accountability is necessary for any organization with deeming authority. The proposed rule states that an accredited laboratory will be out of compliance with the law if one or more condition level deficiencies are identified by HCFA or its agent; it loses its deemed status and is subject to the same sanctions as a non-accredited laboratory. The organization that accredited the laboratory will have this lab added to its "rate of disparity".

This portion of the regulations implies that a given accreditation process is perfect, all laboratories must be perfect, and that HCFA and its Agents are perfectly consistent and never err in their inspections. This is not only contrary to common sense, it is not borne out by the experience of existing laboratory inspection programs. Such a requirement is not only counter-productive for developing mutually beneficial working relationships between HCFA and accrediting bodies, it could also have a chilling effect on those organizations and state agencies which would otherwise seek deeming authority from the federal government.

In addition, the requirement that an accrediting body have a "rate of disparity" of less than 20% is an untried concept and is applied too rigidly in this regulation. Since more than 90% of laboratories falling under CLIA regulations have never been regulated before, we believe the regulation should provide more flexibility for the deemed laboratory and for accrediting organizations.

The Commission opposes the use of "20% rate of disparity" rule at this time. Rather, no percentage grade should be required initially; HCFA should provide a phase-in period of 24 months during which time the appropriateness and use of "rate of disparity" can be studied and the accrediting organizations can adjust to the enormous workload required by these regulations. A cooperative and beneficial working relationship between HCFA and accrediting bodies would be fostered by such an arrangement.

A laboratory found out of compliance during a validation inspection should not immediately be deprived of its deemed status until a final determination is made by HCFA on the merits of appeal by the laboratory and/or the accrediting organization.

The process of review and appeal when the laboratory or the accrediting organization disputes HCFA's determination in a "rate of disparity" case should be delineated by the Agency, published in the Federal Register, and be subject to public comment.

493.511 DEEMING AUTHORITY REVIEW

The Commission commends the Department for providing sufficient opportunity to accrediting bodies to change standards and correct problems. We encourage the Department to re-evaluate other portions of this Proposed

Rule with the same degree of flexibility.

OTHER COMMENTS

HCFA requests public comment regarding the extent to which these rules will change pricing schemes for accrediting organizations. COLA's cost of meeting these regulations will depend in great part on how much information HCFA requests and the form in which it is requested. The cost of providing a simple computer-generated report in electronic format regarding the status of participant laboratories is negligible. However, programming costs may be considerable should reporting requirements be substantial. The cost of submitting proficiency testing data on every participant laboratory will be substantial, and unnecessary as noted above. We anticipate significant postage costs for certified mail to HCFA and participants. There could be considerable staff time and travel expenses devoted to evaluating and challenging "rate of disparity" claims. HCFA's proposed inspection requirements will be extremely costly for the Commission and its enrollees.

HCFA solicits comments regarding organizations that may seek deeming authority for these regulations. The complexity of the regulations implementing CLIA 88 and their interdependence on one another makes it unusually difficult to comment on them piecemeal. As comments are developed, assumptions carry over from one NPRM to another. How the Commission will approach deeming authority will totally depend on what the Final Rules are for quality standards, sanctions, and the granting of deeming authority.

It is the intention of the Commission to seek deeming authority from the Department. However, the COLA Board of Directors will make final decisions regarding application for deeming authority when it has sufficient information to do so.

The Commission believes that the Department has a serious obligation to the public to publish the implementing regulations for CLIA 88 in their entirety for additional public comment after consideration of the public comments provided them on the separate Notices of Proposed Rulemaking.

The Commission on Office Laboratory Assessment looks forward to assisting the Department in all possible ways to achieve our common goal of assuring quality laboratory practices in the United States. If we may be of any further assistance in the development of these regulations, please call us.

Sincerely Yours,

Darroll J. Loschen, M.D.
President

The Commission on Office Laboratory Assessment (COLA) is a voluntary education and accreditation program for physician office laboratories performing clinical laboratory tests. It is COLA's goal to provide clear and specific standards and methods of measuring performance to ensure your laboratory meets all state regulations and is providing the highest quality results. The chart below shows the similarities and differences between the proposed Washington State regulations and the COLA approach to regulating the Microbiology aspects of your lab.

Format		Personnel	Specimens	Materials	Documentation	References	Techniques	Confirmation	Parasitology
STATE REQUIREMENTS	All requirements under General Microbiology Category.	No Training requirements stated	No collection techniques outlines. No handling guidelines provided	Requires use of positive and negative reference organisms to certify new testing materials usable. Certifications must be done periodically. Need to maintain stock of organisms for QC. Visually inspect media before use. Check noncommercial media for functionality.	Must certify the reference organisms as functional. List steps taken for ID of patient specimens. Record QC of commercially made media. Document all visual inspections.	Maintain slides, texts, etc. for references sources.	Instructs the lab to 'follow manufacturers specifications for using the media'.	No confirming procedures stated.	Requires use of calib rated ocular micrometer. Requires reference materials monthly.
COLA APPROACH	Separate areas for Gram Stains, Urine, Genital and Strep culture.	Requires proof of adequate staff training	Requires written instructions. Specimen source guidelines provided. Procedure for delayed testing required.	Visual Exam of all media before using. Discard all materials after expiration date.	Document all visual inspections. Place expiration dates on all materials.	Maintain texts for reference source where applicable.	Provides specific instruction for use of special media, plating, incubating and reading of cultures.	Specifies handling of suspicious colonies and "positive" QC cultures. Requires way of confirming procedure for Group A Strep cultures.	No requirements stated.

Mr. WYDEN. Doctor, thank you very much. Let me say at the outset that I'll have a few questions, but the staff is also going to want to pursue questions with your organizations as well.

Dr. Scalettar, just for a moment, using the HCFA proposed three-tier approach for categorizing labs, in which category would most physician office labs fall?

Mr. SCALETTAR. It's very difficult to say, for example, there are many sophisticated physician office laboratories, many physicians who practice where they—in subspecialty types of medicine, and some of the Level 2 for example contains electrolytes and platelet counts which are necessary for me to practice medicine, for example. So I think it's very difficult to generalize in this particular way. And this is one of the reasons why we are promoting and believe that a new level of category A or Level A should be put forth so that physicians who are specifically using specific tests, nerfologists, or rheumatologists have certain tests that they have to do they personally supervise, they personally do, are extraordinarily important for them to engage in the proper diagnosis and treatment of their patients.

Mr. WYDEN. What's the difference between your proposed Level A and HCFA's proposed Level 1.

Mr. SCALETTAR. Well, it carves out a new level and much can be put into level—from Level 1 into A. It is an attempt to get the process moving. We think that it will be personally supervised by the physician. It is procedures that he or she generally do and there may be considerable overlap, but at least it is an attempt to give quality care that still requires proficiency testing and we think it's a method of moving forward on this process.

Mr. WYDEN. Now, the personnel requirements, as I understand them, for Level 1, that a physician be responsible for the personnel conducting tests and that that person would have to have a high school diploma. Is that your understanding of what Level 1 is?

Mr. SCALETTAR. Yes.

Mr. WYDEN. Now, does this impose a financial burden on the practice in terms of this person's salary?

Mr. SCALETTAR. I don't think so.

Mr. WYDEN. OK. Under HCFA's current proposal, do you all have an estimate of how many physician office labs would fall under the waiver category?

Mr. SCALETTAR. Into the waivered category, I don't know. Do you know? We don't know.

Mr. WYDEN. OK. Now, the absence of data on the number of labs and the type of tests that they are doing and who's conducting the tests obviously troubles the subcommittee and the subcommittee is pleased that the association is serving the membership to determine what exactly is occurring in the physician office lab environment. Chairman Dingell and the subcommittee would like you to report to the subcommittee on the results of the study as soon as they're available. Additionally, it would be helpful if you all could provide to the subcommittee a copy of the questionnaire that you're using and description and methodology that is going to be used in evaluating the questionnaire response so that the subcommittee can assess fully the study results as well. Is that a problem?

Mr. SCALETTAR. We shall be happy to do so.

Mr. Wyden. OK. Now, it would also be helpful for staff to pursue with the association other voluntary efforts to bring about more reliable tests and I would assume you would be happy to discuss that with the subcommittee as well?

Mr. Scalettar. Certainly.

Mr. Wyden. OK. I think we'll just move on to additional matters we will want you to pursue with Ms. Murphy and Dr. Edinger.

Now, Mr. Magazine, is it HEMA's position that the kind of equipment we're talking about today, particularly the type used in physician office labs and mobil labs, are essentially error proof if somebody has proper training?

Mr. Magazine. Training is absolutely critical to operating the equipment that is located in the physician office labs and other laboratories. If it is operated properly, if people are trained and if the equipment is operated properly then the results should be reliable.

Mr. Wyden. Now, in a number of cases the training is provided by a marketing or sales person, isn't that correct?

Mr. Magazine. Training is provided by specially trained individuals in most cases medical technologists, in some case hematologists and others. These are highly qualified individuals. I don't know of situations where sales people are actually doing the training. In the information that we've received from our members who supply 90 percent of the diagnostic equipment is that these people are highly trained themselves in order to be able to give the training to others.

Mr. Wyden. Well, I would like to review that point and have the staff pursue it with your association, because as I remember in the area of the cholesterol testing, there was some concern about training being done by marketing or sales people. I also believe it came up in some of the hearings on POL's, so I would like to have the staff pursue that.

I'm with you, there is no quarrel at all on the proposition that what proper trainers considerably reduces the incidence of errors. The question is what happens absent any kind of rules on how people who aren't properly trained, or sales people and marketing people can slip through and do this training.

Now, are there any kind of studies or background material that would indicate how long the manufacturers' trainers are being trained and by whom?

Mr. Magazine. It varies with the complexity of the tests. Some of the training is done on site, but for more sophisticated equipment training can take up to 2 weeks where people go to training locations in order to be educated on how to operate the equipment.

Mr. Wyden. In the instance of physician office labs, what do you think the typical training period is for a physician office lab?

Mr. Magazine. Yes, we're just not aware of a typical time period because it varies so much with the tests themselves.

Mr. Wyden. We have been told—and again would like to work with you all in fleshing out more detail—that there is a serious concern that a significant number of people in these labs only getting trained for a couple of hours.

Mr. Magazine. We would certainly be happy to work with staff to try to get some more specific information on the amount of time it takes for tests. I would say that there are—there is clearly a variance in the sophistication of the technology and there are tests that are fairly simply to administer, they still require testing, but the amount of time clearly would be less than more sophisticated kinds of equipment.

Mr. WYDEN. Is training provided on recordkeeping, equipment upkeep, and general lab practices?

Mr. MAGAZINE. Yes, it is. There is training. There are good laboratory practices that are spelled out in CLIA 67 and in other locations. There is training on recordkeeping and so on.

Mr. WYDEN. Now——

Mr. MAGAZINE. I'm sorry, I said 67, I meant 88.

Mr. WYDEN. Now, Mr. Magazine, the subcommittee obviously would like to make aggressive voluntary initiatives, a crucial component in our health care system and under Chairman Dingell we have tried to promote those kinds of voluntary initiatives over the years. Can you commit today to include in your impact study a trial program to determine the effects of strengthening training and monitoring programs for the POL's?

Mr. MAGAZINE. To monitoring the training programs?

Mr. WYDEN. Yes. What we would like to do is have in your impact study a kind of trial program to determine the effects of strengthening training and monitoring programs for physician office labs. This would give us an opportunity, again, to get more data to use a voluntary initiative to try to provide some of this information. Is this something that you could check on with your members and get back to us promptly?

Mr. MAGAZINE. I could certainly do that. I could not commit to, at this time, to including in the study, but I certainly could commit to our taking a look at it. We also have partners in the study as you've heard, the AMA, HIDA and others. But we would be willing to take a look at it.

Mr. WYDEN. Do you think it's a good idea personally? I think we're all looking for ways to advance this down the road. This is going to be the longest running battle since the Trojan War and if we don't come up with some fresh ways to get at this, we're going to be sitting here in 5 more years and we're going to have witnesses who are going to attest to problems and we're going to be thrashing around with rules. Just from a personal standpoint, would you think it would be a good idea to try to get some kind of trial voluntary program to examine these effects of strengthening training and monitoring?

Mr. MAGAZINE. Well, Mr. Chairman, we are clearly, as an association, in favor of having the strongest possible training programs to make sure that people are adequately administering the tests and so on. But I can't sit her and say to you that we're aware that there is a significant problem in that regard, and based upon the discussions we had with our members, we feel that the training has been very well handled. That does not imply that we wouldn't be happy to take a good close look at it, talk to our members specifically about it and try to have a finding of fact as to whether or not there is a need for some kind of monitoring or additional—additional training of some kind or of some kind of program.

Mr. Wyden. That would be helpful. I think you can see that my point is, if we could have such a trial program to look at how we might go forward with training and monitoring programs, that's something that could be provided to HCFA. Obviously it is in the interest of your members and the interests of all patients and all consumers to get this done accurately and to get it done cost effectively.

Mr. Magazine. If I may, Mr. Chairman, let me just say that we certainly want to be as helpful as possible to this subcommittee, to HCFA and so on. We supported the law and implementation of the law if appropriately implemented, but we want to be careful that we don't create a solution for a problem that doesn't exist. And I'm not saying there isn't a problem. I'm saying that we don't know that there is one and we would have to take a closer look at that.

Mr. Wyden. OK. Some questions for you Dr. Kroger. Do you believe there's evidence to support the waiver of any test based on error-proofness and what's considered no harm to the patient?

Mr. Kroger. Well, Mr. Chairman, I am a practicing physician as well as the chief executive for COLA and we recognize that there is no test that is foolproof or that does not carry some risk of harm to a patient. It's a matter of estimating what that risk may be.

The commission does not have a position on waivered testing. We require that the laboratories enrolled in our program participate in proficiency testing for any tests that they are performing in the office laboratory.

Mr. Wyden. OK. Do the results of your PT program on physician office labs indicate at this point that there are any error-free tests? I know that you touched on that partially in your first response, but I would be curious whether the results of your PT program address that question.

Mr. Kroger. Well, I would reiterate that there is no perfect test. And proficiency testing has a number of problems associated with it besides the actual performance of the tests. And I would only point out that in the office laboratory pipetting, which is using a graduated device to dilute a substance is only performed on proficiency testing specimens. For the most part, analytes or rather reagents come to the physician prediluted. An error in pipetting will result in an error in proficiency testing results.

What we have found in looking at the laboratories that are now on probation, that is laboratories that have failed two consecutive or two out of four proficiency challenges is that in bacteriology and in hematology there are some problems. These problems can be related to the methodology of the proficiency testing and perhaps to the types of tests, the tests being used and related to personnel training.

In chemistry where the instrumentation is much more automated we are only seeing a very small percentage of failures overall.

Mr. Wyden. Why did the COLA program establish acceptable limits for its proficiency testing program that were wider than those of CAP?

Mr. Kroger. The commission took a different view on grading of proficiency testing than has been the approach in the laboratory area for the last number of years. The existing CDC and CAP grading criteria are primarily driven by the available instrumentation in large laboratories.

Mr. Wyden. I'm sorry?

Mr. Kroger. We looked at what the clinical utility of each of these tests are and how accurate we thought the office laboratory had to be in order to provide useful information to the physician. As a result of that we derived grading criteria that are in some ways different from than the CDC and in some cases actually tighter than their requirements. Others are somewhat looser. But the derivation was totally different.

Mr. Wyden. Does your experience, Doctor, indicate that many of the physician offices that would seek COLA accreditation in the absence of a regulatory requirement?

Mr. Kroger. I think that as the COLA program is more widely understood by physicians that we will see a larger enrollment. I would like to be able to assure that every physician who operated a laboratory would participate, but I don't think that that's the history of voluntary programs.

Mr. Wyden. How much does it cost to accredit a lab under the current program?

Mr. Kroger. The fees for COLA accreditation vary based on the number of disciplines, that is chemistry, hematology and so forth and the number of physicians. And the average is at about $500 a year.

Mr. Wyden. We thank you—we thank you all. The subcommittee staff will want to work closely with you and your organizations in the days ahead and we appreciate your cooperation.

Our last panel, Dr. Loyd Wagner, President, College of American Pathologists, Washington, D.C.

Dr. Wagner, it's good to see you again, and certainly we have talked about these issues often in the past and I think you are aware of the procedures here at the Subcommittee on Oversight and Investigations. Do you have any objection to being sworn as a witness?

Mr. Wagner. No.

Mr. Wyden. Please rise and raise your right hand?

[Witness sworn.]

Mr. Wyden. Doctor, welcome. Let me also advise you that your right to counsel is absolute during your appearance here before the Subcommittee on Oversight and Investigations, you do not desire to be represented by counsel today?

Mr. Wagner. No, I do not.

Mr. Wyden. Let me also note that a copy of the committee rules is present at the table as well.

Doctor, we welcome you. We will make your prepared remarks a part of the hearing record in their entirety. Let me ask you again, in view of the lateness of the hour if you could perhaps summarize your principal concerns so we will have at least a few minutes for some question and answers on these issues that would be helpful. Please proceed.

TESTIMONY OF LOYD WAGNER, PRESIDENT, COLLEGE OF AMERICAN PATHOLOGISTS

Mr. WAGNER. All right. Thank you, Mr. Wyden. I am Dr. Loyd Wagner, President of the College of American Pathologists. I am please to have this opportunity to share the college's views on regulations implementing the Clinical Laboratory Improvement Amendments of 1988. The CAP is a national medical specialty society representing 12,000 physicians who are certified by the American Board of Pathology.

The college believes a quality laboratory medicine in any setting involves documented systems of quality control, quality assurance as well as proficiency testing and appropriate inspections. For nearly 30 years the college has been accrediting laboratories and now inspects and accredits more than 4,000.

Before I proceed to detail the CAP's concerns about the proposed CLIA regulations, let me point out that approximately 12,000 hospital and independent laboratories are currently under regulations very similar to those proposed to CLIA. As a result of the HCFA's final March 14, 1990 rule consolidating CLIA '67 and Medicare standards.

We share the Congressional concern of trying to provide the best quality medicine to ensure public safety. We are concerned, however, that the proposed regulations do not meet this objective despite numerous attempts on the part of the laboratory community to work with HCFA.

My testimony addresses five major issues; proficiency testing, personnel standards, waivered tests, cytology, and private accreditation programs.

The College supports the use of proficiency testing to assess and improve laboratory's performance. However, we believe HCFA has placed a disproportionate emphasis on proficiency testing. The regulations attempt to derive a number that is indicative of inadequate or acceptable performance. No PT sample, regardless of how it is produced, can be identical to a human sample. Likewise, no single sample can be manufactured to reliably assess all instruments and all reagent systems in use.

Given the nature of proficiency testing and the likelihood that even the best labs will experience PT failure, the CAP believes that a laboratory should be required to institute corrective action as soon as PT failure is noted. However, the CLIA certificates should not be revoked or limited—or it should be revoked and limited only after a laboratory has failed to adopt corrective action. Otherwise PT failure could force some hospital laboratories to close critical care units if they cannot obtain laboratory results from off-site certified labs in a timely manner.

The College has revised its proficiency testing program to meet the current Medicare regulations. Despite our best efforts to minimize the regulations cost impact, 1991 price increases were substantial, as much as 150 percent for some surveys for small labs.

The College recommends that the regulations establish personnel qualifications only for the laboratory director and the technical supervisor. In general the laboratory director should be a physician with training and experience in clinical laboratory services or a laboratory specialist with a doctoral degree in physical, chemical or biologic science with appropriate training and experience. The qualified director can determine what levels of training, experience and formal education are needed for other personnel.

Moving to the certificate of waiver under the proposed regulations, laboratories that perform only one or more of the 28 tests may qualify for a certificate of waiver. HCFA has determined that these tests have an insignificant risk of harm if results are erroneous and have a simply testing methodology. It is the CAP's belief that no incorrect test result is risk free in regard to potential patient harm. Having no standards for these tests could allow them to be performed by improperly trained personnel with no proficiency testing or quality controls required. Analytic process errors cannot be detected unless there is quality control and PT in place.

CAP believes that all test procedures performed, including waivered tests, should be subject to a documented quality control program and proficiency testing if available.

We have been asked whether PT data could be useful in determining whether specific tests should be included or excluded from the waivered list. The College believes that a high success rate in proficiency testing for a particular test demonstrates the value of PT for issuing good laboratory performance, but does not mean that PT should be discontinued. The proper use of PT is only to identify analytic system problems.

The College has serious concerns with both the current and proposed cytology regulations which we have expressed to CLIA or to HCFA on several occasions. Although cytology regulations are now in effect for hospital and independent laboratories participating in Medicare, HCFA has not been able to enforce them. No one has the cytology PT program which meets their specifications.

The College did not apply for recognition of a cytology program because we also do not have a program that meets those regulations. We have discussed basically only two of our major concerns in the regulations. First of all the biannual proficiency testing and on-site PT. Each individual, including the pathologist, who examines Gyn slides must be tested twice each year on 20 slides for each proficiency testing event.

The College believes that requiring biannual proficiency testing with one event to be on-site is impractical. The system can simply not generate enough slide material in any reasonable timeframe to meet the demands of a 20-slide PT event. There is no evidence that such frequent testing is necessary or that it will enhance quality.

Remedial actions for a PT failure are excessive and have no scientific validity. The regulations would force, under the present system, laboratories to either discontinue cytology services or substantially increase backlogged cases because lab personnel would have to spend their time rescreening previously reviewed slides. Delays in reporting a diagnosis to the attending physician could unreasonably delay therapy to a patient.

The College has urged HCFA to consider a mailed glass slide program for PT testing and the College has developed an educational CP or PAP program, a PAP program.

In 1991, 600 laboratories will participate and we anticipate expanding that in the next 2 years. Slide availability is a major factor which limits its expansion. The College program provides onsite glass slide material which measures cytology laboratory performance and simulates real life laboratory practice. We feel that continuous immediate feedback to participants, statistical review of data and monitoring of information will result in improved performance in the cytology laboratory.

Finally, the College believes CLIA will be unworkable unless HCFA is willing to work with private accrediting bodies such as CAP, COLA, JCHO. The laboratory accreditation program of CAP is a comprehensive peer review program that examines all aspects of quality assurance in the laboratory and is considered the most comprehensive and demanding in the world.

The HCFA proposed regulations on granting deeming authority to private accreditation organizations appear only to ensure that a private program is identical in every detail to HCFA's regulatory requirements.

The College and other private programs must be granted flexibility to design their programs to meet the needs of laboratories seeking private accreditation.

In summary, the College supports efforts to ensure public access to high-quality lab services. Documented systems of quality control and quality assurance and participation in proficiency testing are important steps for maintaining and improving laboratory performance. We are concerned that the proposed regulations will impose costly requirements on laboratories and will not result in improving laboratory quality.

Mr. Chairman, I have outlined our concerns with these regulations. The College stands ready, as always, to work, not only with Congress but with HCFA, to develop workable regulations and I will be glad to answer any questions you have.

[Testimony resumes on p. 238.]

[The prepared statement of Dr. Wagner follows:]

STATEMENT OF THE
COLLEGE OF AMERICAN PATHOLOGISTS

Good morning Mr. Chairman, my name is Loyd R. Wagner, MD. As President of the College of American Pathologists, I am pleased to have this opportunity to share with you the College's views on the development of regulations implementing the Clinical Laboratory Improvement Amendments of 1988. The CAP is a national medical specialty society representing 12,000 physicians who are certified by the American Board of Pathology. CAP members practice their specialty in community hospitals, independent medical laboratories, academic medical facilities, medical examiner/coroner offices, and federal and state health facilities. The CLIA '88 legislation and attendant regulations significantly impact on the practice of pathology and laboratory medicine.

The College was founded on the belief that quality laboratory medicine involves documented systems of quality control and quality assurance measures, proficiency testing and inspections. For nearly 30 years, the College has been accrediting laboratories, and currently inspects and accredits more than 4,000 laboratories in the United States. Our accreditation program relies on a system of peer review using approximately 2000 practicing pathologists and thousands of technologists and clinical scientists.

Before I proceed to detail the CAP's concerns about the proposed CLIA '88 regulations and the process for developing those regulations, let me point out that approximately 12,000 hospital laboratories and independent laboratories participating in Medicare or engaged in interstate commerce are currently under regulations very similar to those proposed for CLIA '88. These current regulations are a result of HCFA's final March 14, 1990, regulations which consolidated CLIA '67 and Medicare standards for laboratories. You will see that many of the problems we have with the proposed CLIA '88 regulations are already affecting hospital and independent laboratories. I believe it is very telling that the March 1990 regulations, while in effect, have yet to be implemented in the areas of proficiency testing for cytology because no organization can comply with the unreasonable requirements of the regulation.

We share the Congressional concern of trying to provide the best quality medicine to ensure public safety and prevent disease. We are concerned that the HCFA regulations do not meet this objective despite numerous attempts on the part of the laboratory community to work with HCFA on developing a workable regulation. The first part of our testimony addresses major issues in the areas of proficiency testing for clinical laboratory services, personnel standards for the laboratory and the concept of waivered tests. Then we address the issues surrounding regulations to implement the CLIA '88 requirements for national standards for quality assurance in cytology services. Lastly, we focus on recognition of private accreditation programs for compliance with CLIA certification standards.

PROFICIENCY TESTING FOR CLINICAL LABORATORY SERVICES

The College supports the use of proficiency testing to assess and improve the laboratory's performance. However, we believe HCFA has placed a disproportionate emphasis on proficiency testing (PT) as the single means of assessing laboratory performance in the final March 14, 1990, regulations and the proposed CLIA '88 regulations. The regulations attempt to derive a "number" that is indicative of "inadequate" or "acceptable" performance, which is a much too simplistic approach. Limitations of proficiency testing are well-documented. No PT sample, regardless of how it is produced, can be identical to a human sample. Likewise, no single PT specimen or sample can be manufactured to reliably assess all instruments and all reagent systems in use.

The above recognized limitations of proficiency testing must be taken into account when using PT data to determine whether a laboratory is producing accurate, reliable results on patient samples. A single "target" value cannot be used for many analytes because of significant matrix effects or a difference in laboratory methodologies for measuring analytes. Although the College PT program has received HCFA approval for 1991, we remain concerned that the PT grading system developed by HCFA is flawed and should allow more flexibility to the PT provider.

Under the uniform proficiency testing (PT) program regulations, laboratories must attain an overall score of at least 80 percent per analyte and in each specialty or subspecialty for each PT event; immunohematology requires 100 percent for ABO, Rh, and compatibility testing. Unless an acceptable reason is submitted at the time of a PT event, non-participation results in a score of 0. Failure of two consecutive PT events or two of three consecutive PT events is considered unsatisfactory performance.

If a laboratory fails to participate successfully on one analyte in a specialty or subspecialty, certification for the entire specialty or subspecialty is subject to suspension. It is unreasonable to ask a laboratory to stop all chemistry testing if it has two consecutive "unsatisfactory" events for chloride only. Forcing a hospital to send out its blood gases and other tests that are essential to critical patient care because the hospital "failed" chloride will be extremely detrimental to the facility's ability to provide critical patient care. Surgical units, coronary care units and other critical care units in some hospitals would have to close as referral laboratories cannot provide laboratory determinations on an emergency basis, especially in rural areas.

Once a laboratory's certification in a specialty or subspecialty has been revoked or suspended, it cannot be reinstated until successful participation in three consecutive PT events has been completed. Denying a laboratory reinstatement in an entire specialty or subspecialty until successful performance in three consecutive proficiency testing events has been accomplished is unreasonable. The CAP believes that a laboratory should be required to institute corrective action when PT failure occurs. Revocation, limitation, or suspension of the CLIA certificate should occur only after a laboratory has failed to adopt corrective action to improve its performance.

The uniform proficiency testing regulations have had a tremendous impact on the structure of the College's PT programs and the cost of the program to participating laboratories. The College has revised its proficiency testing program to meet the uniform proficiency testing regulations. Of the 81 CAP Surveys offered in 1990, 44 were substantially reconfigured and 14 new surveys were introduced in 1991. Regulatory requirements to increase the frequency of challenges for each analyte to five per quarter caused substantial cost increases. Despite our best efforts to minimize the regulation's cost impact, 1991 price increases were substantial–as much as approximately 150 percent for some high volume surveys for small laboratories.

The College has the ability to expand its PT program to accommodate additional participants. However, substantial advance notice (approximately 18 months) of participant increases is necessary because PT samples must be ordered from manufacturers who need time to adjust production capabilities. In addition, the College must consider the capability of computer systems to handle increased data processing demands.

PERSONNEL STANDARDS

The proposed CLIA '88 regulations establish education, experience, and training requirements for the laboratory director, general and technical supervisors, technologists, cytotechnologists, and technicians. Proposed personnel standards differ depending on the type of test performed. If adopted, these standards will result in major additional costs for laboratory services. Many laboratories would be forced to close because of high costs or the inability to find personnel meeting the proposed qualifications. Physician office laboratories and rural hospitals will find it extremely difficult if not impossible to meet the requirements. The consequences will be reduced patient access, increased cost, and delays in report results.

The proposed rule would permit individuals who passed the Public Health Service proficiency exam on or before July 1, 1970, to serve as directors of laboratories and as technical supervisors. The College believes this provision, which allows individuals who have no formal medical/science education or training to direct hospital laboratories, is inconsistent with the intent of CLIA '88.

The College recommends that the CLIA '88 regulations establish personnel qualifications for the laboratory director and the technical supervisor based on Medicare conditions of participation for hospital laboratories in existence prior to March 14, 1990, and CAP standards for laboratory accreditation. In general, the laboratory director should be a physician with training and experience in clinical laboratory services or a laboratory specialist with a doctoral degree in physical, chemical or biological science with training and experience in clinical laboratory services.

It is unnecessary to include standards below the technical supervisor level. The training and experience requirements of these personnel should be the responsibility of the qualified laboratory director. Laboratory directors would be responsible for determining, based on the complexity of tests performed, what level of training experience and formal education are needed by laboratory personnel. In many situations the laboratory director will rely on established private certification programs, such as that of the American Society of Clinical Pathologists (ASCP), to help in identifying appropriate personnel.

The reality is that every laboratory has differing personnel needs based on test mix, instrumentation, laboratory environment, size, hours of services, and workload. Each laboratory therefore will have to use a unique combination of personnel at all levels in order to satisfy its service demands. The quality of work is best measured by a combination of documented quality control and quality assurance measures, on-site inspections and, to some degree, proficiency testing.

WAIVERED TESTS

Under the proposed CLIA '88 regulations, laboratories that perform only one or more of the 28 tests on the certificate of waiver list may get certificates of waiver.

HCFA has determined that these tests have an insignificant risk of harm to the patient if results are erroneous and have a "simple" testing methodology. It is the CAP's belief that no incorrect test result is "risk free" with regard to potential patient harm. Certificate of waiver tests, regardless of where they are performed are exempt from proficiency testing (even in patient care settings where participation in PT is standard), quality control, personnel requirements, and routine inspections. This represents a step backward in efforts to assure quality laboratory testing.

The problem that results from having no standards for these tests is that they can be performed by improperly trained personnel and there are no proficiency testing or quality controls required. This could be a serious public health threat. Analytic process errors cannot be detected unless there is quality control and PT in place.

CAP believes a "certificate of waiver" should be issued only to physician offices where tests are performed for the physicians' own patients. Only tests that do not involve complex methods or instruments and are for the immediate diagnosis and/or treatment of the physician's patients or FDA approved for home use should be "waivered." All test procedures performed, including "waivered" tests should be subject to a documented quality control program and proficiency testing should be performed if available.

We have been asked whether PT data could be useful in determining whether specific tests should be included or excluded from the proposed waivered test list. The theory, as we understand it, is that if a high percentage of PT participants perform successfully for a test (e.g, urinalysis), then there is less risk of harm to the patient if the test is waivered. The problem with this approach is that it overlooks one of the major purposes of participating in proficiency testing: the monitoring of test performance and early identification of problems so that corrective action can be taken before harm results to patients. The College believes that a high success rate in proficiency testing for a particular test demonstrates the value of PT as a quality control mechanism for assuring continued good performance by the laboratory. High PT success rates should not mean that PT can be discontinued.

CYTOLOGY REGULATIONS

The College has serious concerns with the cytology regulations that are now in effect for laboratories participating in Medicare and are proposed under CLIA '88, and has provided HCFA with detailed comments on these regulations on several occasions.

- In March 1990, we wrote to the HHS Secretary objecting to draft Medicare cytology regulations that were then under development. We urged the Secretary to suspend their publication and submitted detailed comments pointing out problems with the rule. We offered experts in cytopathology to work with

HHS regulation drafters to develop a more valid approach. Despite our concerns, the regulations were adopted as final Medicare rules on March 14, 1990, with a request for comment.

- In May 1990, we commented to HCFA that the final Medicare cytology rules would limit access and significantly increase the cost of gynecologic cytology due primarily to proposed proficiency testing, remediation and workload requirements which do not reflect the "real-life" practice of cytology. Comments from many College members in rural areas indicated that laboratories now performing cytology services would cease to offer the service. Small facilities with one or two cytotechnologists and/or one or two pathologists will either stop providing cytology or be forced by periodic proficiency test event failures and unduly burdensome remediation requirements to cease providing the service.

- On May 21, 1990, essentially the same cytology regulations were reproposed as part of the proposed rule to implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). The College commented a third time urging HCFA to withdraw the regulation and to work with the College and other organizations with technical expertise to develop a practical regulatory framework for cytology services.

Although cytology regulations are now in effect for hospital and independent laboratories participating in Medicare, as a practical matter HCFA has not been able to enforce them. In fact, the authority to establish a cytology proficiency testing program has been in place since the Clinical Laboratory Improvement Act of 1967. Previous efforts by the Centers for Disease Control (CDC) to develop such a program illustrate the difficulty in establishing such programs. The onerous requirements for cytology proficiency testing, which became effective on January 1, 1991, have not been implemented because there are no proficiency testing programs that can meet the requirements. The College did not apply for recognition of a cytology PT program because we do not have a program that meets HCFA's requirements. It is apparent to us that the usual process of regulation proposal followed by request for comment is not generating workable regulations that will effectively provide access to quality cost-effective cytology services.

The following are some of our major concerns with the cytology regulations and our recommendations for addressing these concerns:

Biannual Proficiency Testing (PT) and On-site PT. The regulation requires each individual, including a pathologist, who examines gynecologic preparations to be tested twice each year on 20 slides for each proficiency testing (PT) event. One unannounced on-site PT event will be conducted in each lab once a year; no less than four announced off-site testing events will be conducted annually in each state. The requirement for 20 slides is excessive and is not required by the CLIA statute.

The College believes that requiring biannual proficiency testing with one event to be on-site is impractical. The system simply cannot generate enough slide material in any reasonable time frame to meet the demands of a 20 slide PT event on a twice a year basis for all individuals who review slides. A major problem is the ability to establish a national program that tests and grades all participants in an equitable manner. The difficulty is in obtaining slides with some degree of uniformity. There is no evidence that such frequent testing is necessary or that it will enhance quality. The only two states that currently administer cytology proficiency testing programs are New York and Maryland, and they test on an annual or biennial schedule. Requiring unannounced on-site testing will disrupt the lab, and it is likely individuals may not be available during the on-site visit – due to continuing education training, vacations, and workload requirements.

Remedial Actions for PT Failure. If an individual fails a PT event, the lab must reexamine the last 500 negative gynecologic slides the individual evaluated before the failed testing event. In addition, the lab must have another individual reexamine all of the subsequent gynecologic slide evaluations of the individual who failed until that individual is retested and achieves a passing PT score.

The arbitrary 500 slide rescreening requirement following a PT failure is excessively punitive and extremely disruptive to laboratories. Given the regulation's workload restrictions (120 slides per day; 80 previously unevaluated and 40 for quality control/assurance) it would take 12.5 days of a cytotechnologist's or pathologist's time to complete the review. The small laboratory where cytology slides are evaluated by only one or two persons would be in jeopardy because a PT event failure would remove the individual from the work force. This is too harsh a result for a PT program that is new and unproven. Backlogs of unscreened cases, which are already a serious problem in many laboratories, will increase.

The above requirements should be eliminated because they have no scientific validity, do not improve the quality of cytology services, and are excessively punitive. They would force laboratories to either discontinue this service or substantially increase backlogged cases because screeners would have to spend their time rescreening previously reviewed slides. This would cause ever increasing delays in reporting a diagnosis to the attending physician and could unreasonably delay therapy to the detriment of the patient.

The College recommends that if a laboratory fails a proficiency testing event, it should be retested within 30 days. Remediation then could be imposed only after failure of the second consecutive proficiency testing event. It is our opinion that this is a more reasonable approach to improve the quality of cytology laboratory services.

Rescreening Negative Slides. The regulations require reexamination of at least 10 percent of all gynecologic cases interpreted as negative for premalignant or malignant conditions. There is no statistical validity to the 10 percent rescreening requirement. Articles have been published in the scientific literature that clearly indicate the futility of this technique for identifying "false negative" cases. A statistical analysis and discussion to support our criticism of the 10 percent rescreen requirement has been provided to the Health Care Financing Administration. This requirement should be replaced with a scientifically valid system for promoting quality control in cytology which focuses on other elements of quality assurance such as inspection, patient follow-up, and biopsy correlation.

Workload Limitations. Laboratories must ensure that individuals evaluating cytology preparations examine no more than 120 slides (including non-gyn-preparations) in any 24-hour period. No more than 80 of these slides may be previously unevaluated slides; the remaining 40 slides may be examined for quality control/assurance or PT purposes only. The rule suggests that the 40 additional slides allowed for rescreening and quality control are less important and require less accuracy than patient samples. This is illogical in that both are at least equally important. In fact, the rescreening and quality control activity may be even more critical.

The number of slides each full-time cytotechnologist can review in an eight-hour day should be determined by the laboratory director (or technical supervisor) based on the particular environment, personnel, and workload of the laboratory. Such flexibility allows cytotechnologists who are clearly capable of performing above and beyond the "usual" workload capacity to do so; it also negates potential efforts to force cytotechnologists with less capability to attain a specified "number." While 120 slides per day may be a realistic limit, the laboratory director should have the flexibility to decide the mix of patient or quality control specimens examined.

Proficiency Testing (PT) Scoring. To be approved for PT testing for gynecologic examinations in cytology, an approved PT program must provide 20 glass slide preparations per test set and assess the accuracy of each individual's responses. A proficiency testing program in cytology must provide previously "referenced" slides: "positive" slides that have been confirmed by tissue biopsy and "negative" slides that have been confirmed by 95 percent consensus agreement. The format and terminology for reporting cytopathology proficiency testing results is taken from the 1988 Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnosis. Individuals must achieve a passing score of 80 percent of acceptable responses for each testing event. A passing score of 80 percent is also required to reinstate an individual after failure of a PT event.

The College recommends the proposed scoring system be revised to assess the different functions of cytotechnologists and pathologists and reflect how cytology is truly practiced. Cytotechnologists should be graded only on their ability to categorize the slides as either "negative" ("within normal limits") or "abnormal" ("atypical"). Pathologists should be evaluated only on their ability to separate the "abnormal" slides into "benign" abnormalities and dysplasias and/or premalignant or malignant abnormalities. A diagnosis of dysplasia, regardless of degree, is an indication for further diagnostic procedures or evaluation. Individuals should not be penalized for failure to agree with the PT program's interpretation of the degree of dysplasia.

The Bethesda terminology system is very new, is not extensively used in practice in this country, and is not currently being used by any of the state cytology testing programs. It is inappropriate to grade practicing cytotechnologists and pathologists using a system of terminology with which they are unfamiliar and which has not gained universal acceptance. We understand that some clinicians have serious reservations with the Bethesda system and significant revision of the system is currently being considered.

Cytology Test Result Reporting. The proposed CLIA '88 regulations require laboratories to report results of all biopsy-proven cases of cervical cancer to state health departments. In addition, laboratories must report all malignant and pre-malignant gynecologic cases (dysplasia, cervical intraepithelial neoplasia, or all squamous intraepithelial lesions, including human papillomavirus associated changes) to their respective state health departments. This requirement should be eliminated; it is clearly an invasion of patient privacy and will cause increased data burdens for laboratories as well as state health departments. Existing systems are not capable of handling this volume of data and will be overwhelmed.

The College PAP Program. The College has urged HCFA to consider a mailed glass slide program for cytology proficiency testing. The CAP has developed a mailed glass slide education program on a pilot basis and has been administering it for three years. The program is known as the CAP Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP). We have found this program to be effective in identifying problems in cytology testing and for determining areas in which laboratories can participate in remedial education actions.

PAP was developed in 1988 and was based upon earlier attempts at such a program in the early 1980's. For the 1989 pilot project, more than 200 laboratories, including more than 300 pathologists and cytotechnologists, participated. In 1990, 301 labs with more than 550 pathologists and cytotechnologists participated. In 1991, 600 laboratories with about 2100 pathologists and cytotechnologists will participate. We anticipate the College will be able to expand the program to over 2000 laboratories in the next two years. This growing number of participants demonstrates the profession's commitment to quality in cervicovaginal cytology. However, obtaining a sufficient number of slides to use in the PAP Program is the major factor in limiting the expansion of the program.

Glass slides with known diagnoses have been solicited from participating laboratories. The slides include a variety of normal, inflammatory, reactive, pre-malignant, and malignant cervicovaginal cases. Cases are selected by the CAP Cytopathology Committee at slide "marathon sessions." Each case is reviewed by two or more CAP Committee members, who are experienced cytopathologists and cytotechnologists. In addition to CAP members, the Committee includes liaison members from the Centers for Disease Control, National Cancer Institute, American Society of Cytology, and American Society of Cytotechnology. On occasion, local guests who are widely experienced in cytopathology practice are invited. This allows each slide to be reviewed by at least four persons.

Each laboratory receives four mailings per year, which include five glass PAP smears (20 cases per year) and a questionnaire related to practice. Answers are returned to CAP via mail or fax (over 90 percent use the fax option). CAP then returns by fax the reference diagnosis and the slide performance on the individual test slides. This allows immediate feedback to the laboratory and the laboratory may keep the slide for an extra day or two for review as an educational exercise.

For purposes of quality assurance, slide interpretations are carefully monitored by CAP staff and Committee members. If a slide is not consistently interpreted, review of that slide by the Committee may result in its removal from the test process or identify a specific education need. The ongoing survey questionnaire concerns practice patterns in cervicovaginal cytology. These data are also returned to participants for their interest and use in their own laboratories. Survey questions have focused on such things as criteria for unsatisfactory specimens, use of the Bethesda reporting system, other terminology, and report formats.

In 1989 and 1990, information has been compiled on more than 650 participants and includes more than 20,000 answers. Goals for the Program include: compilation of normative data for test slides, incidence and analysis of false negative and false positive diagnoses, and information about typical problems in cervicovaginal cytology differential diagnosis. This information is shared with participants in periodic summary reports so that they may compare themselves with their peers. Problem cases and recurring interpretive problems from the test material are presented at national CAP conferences.

In summary, the PAP Program provides on-site, glass slide material which measures cytology laboratory performance in a fashion which simulates "real life" laboratory practice. In this way, CAP is able to measure laboratory performance and the laboratory is able to measure individual cytotechnologist performance. We feel that continuous, immediate feedback to participants, statistical review of data, and monitoring of information from participants will result in improved performance in the cytology laboratory. Expansion of the program is possible because of the willingness of CAP members and cytotechnologists to contribute material, and the available expertise of CAP Cytopathology Committee and the cytopathology community. CAP believes that such a program will ultimately contribute to continuous performance improvement in cervicovaginal cytology screening and interpretation.

A mailed glass slide program such as the PAP Program described above has many advantages. Results can be processed in a timely manner and consequently laboratories will be able to take earlier remedial actions. It simulates normal working conditions while causing minimal disruption to laboratories. The PAP Program allows technologists to remain in laboratories so lost work time is minimized. The Program is effective and minimizes additional costs passed on to patients. An immediate educational component is provided which helps to promote continuous improvement.

In conclusion, we believe that problems in cytopathology screening are rarely related to a lack of skill, intent or neglect by cytotechnologists or pathologists. The Pap smear for screening for cervical cancer is a complex and subjective process involving several types of professionals in the procurement, preparation, evaluation, and reporting of cellular abnormalities. Only through careful definition of identified problems and the promotion of educational activity will performance be enhanced. The PAP Program was designed to address these goals and will therefore contribute to quality improvement.

RECOGNITION OF PRIVATE ACCREDITING BODIES

The CAP's Laboratory Accreditation Program is considered the most comprehensive and demanding in the world, and there is incontrovertible evidence that laboratory performance has consistently improved in those facilities accredited by CAP. The Laboratory Accreditation Program (LAP) is a comprehensive peer review program that examines all aspects of quality assurance in the laboratory, including test methodologies, reagents, control media, equipment, specimen handling, procedure manuals, test reporting, daily quality control activities, proficiency testing and monitoring, personnel safety, and the overall management practices that distinguish a quality laboratory. The accreditation process involves pre-inspection documentation of these activities, an on-site inspection of between one and three days by teams of two to ten pathologists and medical technologists, and corrective action on deficiencies identified by the inspection team.

The CAP Laboratory Accreditation Program was afforded equivalency under CLIA '67 and retained such until the recent passage of CLIA '88 legislation. Interstate laboratories accredited under this equivalency have consistently performed at high levels of quality, and none have ever had their exemption from licensure revoked by the Centers for Disease Control (CDC) or the Health Care Financing Administration (HCFA).

Major changes have been made in the Laboratory Accreditation Program in the past eighteen months to streamline the accreditation process and to better address potential needs of CLIA '88. The principle guiding all modifications has been to maintain the professional peer review and educational nature of the program while maximizing the uniformity with which it is administered.

In order to facilitate communications with volunteer inspectors and the professional review of inspection data by the commissioners, the program has expanded from eleven to fourteen regions (including one overseas region). A new computer system that provides a mechanism for monitoring all aspects of the process has been implemented centrally with all regional offices networked.

A major initiative toward more efficient and effective processing of inspection and proficiency testing information has resulted in the addition of a team of senior medical technologists who perform the initial review of the laboratory's action plan to correct deficiencies. They also evaluate the lab's enrollment and performance in proficiency testing and present their findings to the commissioners who make the accreditation recommendation.

HCFA has proposed regulations on granting and withdrawal of deeming authority to private non-profit accreditation organizations and to state licensure agencies. As written, the regulations appear to be simply a mechanism to ensure that a private accrediting organization's program is identical in every detail to HCFA's regulatory requirements rather than a mechanism to approve accrediting organizations with standards that are "equivalent to or more stringent" than those of HCFA as required by CLIA '88.

The College is concerned that the, as yet unspecified, HCFA process for determining equivalency will rely on a line item "crosswalk" of detailed HCFA requirements to those of the private accrediting body. The College and other accrediting programs must be granted sufficient flexibility to design their own programs to meet the needs of laboratories seeking private accreditation as an alternative to HCFA inspection. One way of determining whether a private program provides reasonable assurance that CLIA or Medicare conditions are being met is to determine which standards are critical and essential to patient "outcomes." A comparison of those standards to the private accrediting organization's standards need not require identical documentation and procedures for assessing laboratory compliance with the essential standard. The comparison should focus instead on whether the procedures or other requirements of the accrediting organization can provide reasonable assurance that a laboratory meets the basic intent of the CLIA standards. The College would be pleased to work with HCFA staff to undertake a critical analysis of CLIA standards (once they are finalized) to determine what kinds of comparisons are needed to provide a reasonable assurance of equivalency.

When CLIA regulations are final, federal jurisdiction will extend to a large number of additional laboratories. Some estimate that the 12,000 laboratories currently subject to regulation under Medicare and CLIA '67 will increase to over 100,000 when CLIA '88 is implemented. The College LAP Program can be expanded to cover a very small proportion of the newly regulated laboratories that might seek private accreditation. We rely on volunteers to contribute time and effort to the inspection process. The availability of inspectors limits our ability to expand.

The Commission on Office Laboratory Assessment (COLA) which was cosponsored by the CAP, American Society of Internal Medicine (ASIM), American Academy of Family Practitioners (AAFP), and American Medical Association (AMA) has the ability to accredit physician office laboratories. The COLA approach of documenting laboratory performance through mailed questionnaires to the physician office lab, random inspections and inspections for cause is a reasonable approach to assuring physician office laboratory compliance with CLIA standards.

SUMMARY

The College supports efforts to ensure public access to high quality laboratory services. Documented systems of quality control and quality assurance and participation in proficiency testing are important steps for maintaining and improving laboratory performance. We are concerned that proposed CLIA '88 regulations will impose costly requirements on laboratories and will not result in improving laboratory quality.

The College has outlined its major concerns with the proposed CLIA '88 regulations and the regulations that are currently in effect for laboratories participating in Medicare. We have made recommendations for changes to the regulation to HCFA and now to the Congress. The College stands ready to provide assistance and advice in moving toward a workable regulation to implement CLIA '88.

USER\SMW\02MAY91.DUP

Mr. WYDEN. We thank you. You're being most cooperative, and we've got a problem, because we have vote on the Floor and we have to be out of this room. I think what I'm going to try and do is see if I can get a couple of questions in and with your indulgence we will have Ms. Murphy and also, of course, the minority, submit questions in writing as well.

Mr. WAGNER. Fine.

Mr. WYDEN. Do you know of any evidence, Doctor, to support the error proofness of any of the waivered tests or data that the erroneous test results would not have some impact on patient health?

Mr. WAGNER. Do I have any data? No, sir.

Mr. WYDEN. OK. You mentioned a certificate of waiver for physicians performing tests on their own patients, on tests that do not involve complex methods or instruments and are for immediate diagnosis and/or treatment a physician's patients or FDA approved home-use tests. But you also say that all tests, including the waivered tests should have documented proficiency testing and quality control programs. The question, I think, that the subcommittee is interested in is how are both of these things obtainable? The question of how they can be waivered and at the same time beget the kind of PT and quality control that you and the subcommittee want. Can you explain how these two can be——

Mr. WAGNER. Well, let me explain first of all——

Mr. WYDEN.—somehow put together.

Mr. WAGNER. Yes. Mr. Wyden, the opinion of most of us in the College is that there is no test that should be waivered first of all. The policy of the College was developed by the Board of Governors in response to CLIA '88 which clearly sets up a category of waiver. And we felt that because of this there would be a need to limit it strictly to the physician's office laboratory and get away from the off-site—the testing in shopping centers and this type of thing where there is no control and with no controls whatsoever on personnel.

Also, on the FDA we felt that since the FDA approves them for home use, that probably it made sense to allow that to be waivered in the physician's office laboratory as well. We recognize that there are no requirements for PT or QC standard, but we feel that any test that's performed has to have those as components of knowing whether or not it is accurate and can be used for patient diagnosis and treatment purposes.

Mr. WYDEN. From the information we heard from Dr. Kroger, it would appear that a modest number of physicians have voluntarily enrolled in COLA or proficiency testing and this offers further evidence that would indicate that without the mandatory requirements it's going to be hard to get extensive levels of participation. Now, clearly, the subcommittee has made it clear that it wishes to encourage voluntary programs, that it's our view that they are vital part of any regulatory program, but it seems that there is still going to be a need for some regulation in order to make sure that we get the kind of participation we want. We are curious about your view on that.

Mr. WAGNER. Well, I think you're right, Mr. Chairman, that some degree of regulation will be necessary. We would hope that the regulations would be crafted in such a manner that the goals can really be achieved. We feel that the model of COLA, for instance, for physician office laboratories is a pattern and a model which could be utilized to regulate the physician's office lab.

Mr. WYDEN. Well, Doctor, you know, again, because of votes on the floor and the lateness of the hour, I'm going to ask that the staff on both sides, the majority and minority, offer their additional questions to you.

I want to thank you personally for your cooperation as well. I think you know that CAP furnished my own subcommittee important data about many of the laboratories that you accredit and that has been referred to. So we thank you for your cooperation and we will excuse you at this time.

Mr. WAGNER. Thank you.

Mr. WYDEN. The Subcommittee on Oversight and Investigations is adjourned.

[Whereupon, at 2:56 p.m., the subcommittee adjourned.]

[The following material was submitted for the record:]

SENT BY:ST. LOUIS, MO 63101 ; 5- 1-91 ;12:52PM ; BIRENBAUM & ASSOC.→ 12028576395--110;# 2/ 3

AAB
AMERICAN ASSOCIATION OF BIOANALYSTS
Suite 918 • 818 Olive Street • St. Louis, Missouri 63101 • (314) 241-1445

1990-91
BOARD OF DIRECTORS

President
SHIRLEY CRESSWELL, BLD
Professional Laboratory Service
1514 North Michigan Avenue
Saginaw, MI 48602
(517) 771-6030

President-Elect
WILLIAM W. TRIEBER, BLD
Ygnacio Laboratories
120 La Casa Via, Suite 102
Walnut Creek, CA 94598
(415) 939-5344

Vice-Presidents
HAROUTUNE DEKIRMENJIAN, Ph.D., CLD
National Psychopharmacology Lab., Inc.
9320 Parkwest Boulevard
Knoxville, TN 37923
(615) 690-8101

THEODORE J. PASSON, JR., Ph.D., BCLD
Hoyle-Passon Laboratories, Inc.
211 White Horse Pike
Audubon, NJ 08106
(609) 547-8421

Secretary/Treasurer
EDWARD H. EATON, BLD
Claymont Medical Laboratory
1320 Philadelphia Pike
Wilmington, DE 19809
(302) 798-2520

Regional Administrative Secretaries

Midwestern Region
DAVID KOUCHE
Bio-Path Laboratories
36001 Euclid Avenue
Willoughby, OH 44094
(216) 946-1326

Western Region
ELIZABETH T. LOWE, BLM
Allied Medical Laboratories
20392 Town Center Lane
Cupertino, CA 95014
(408) 252-8336

Southern Region
NICHOLAS T. SERAFY, JR.
AAB Proficiency Testing Service
205 West Levee Street
Brownsville, TX 78520
(512) 546-5315

Eastern Region
ROBERT J. KOROSKI, Ph.D.
Friends Medical Laboratory
5820 Southwestern Boulevard
Southwestern Professional Building
Baltimore, MD 21727
(301) 247-4417

Manager Representative
MARY JANE BURT
Burt Medical Laboratory
126 Sherman Avenue, Box 1655
New Haven, CT 06507
(203) 865-2147

Supervisor Representative
SHAWN J. HABTEY, MS
Ballentine & Shub Laboratories
1111 Park Avenue
Baltimore, MD 21201
(301) 523-0043

Section Representative
NICHOLAS T. SERAFY, BLD
AAB Proficiency Testing Service
205 West Levee Street
Brownsville, TX 78520
(512) 546-5315

COMMITTEES

Government & Professional Relations
ALVIN M. SALTON, BLD
Community Medical Laboratories
293 Main Street
Metuchen, NJ 08840
(201) 494-5600

Division of Professional Services
Proficiency Testing Service
NICHOLAS T. SERAFY, BLD, Director

Continuing Education
SHIRLEY CRESSWELL, BLD, Chairman

Constitution & Bylaws
ALVIN M. SALTON, BLD, Chairman

Board of Scientific Advisors
DAVID KOUCHE, Chairman

Administrator
DAVID BIRENBAUM

Associate Administrator
MARK S. BIRENBAUM, Ph.D.

May 1, 1991

The Honorable John D. Dingell
Chairman
Subcommittee on Oversight and
  Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The American Association of Bioanalysts (AAB), which represents directors, owners, managers, and supervisors of independent community clinical laboratories across the country, is a strong supporter of your efforts and those of the Energy and Commerce Committee to improve the quality of laboratory testing. AAB also maintains one of the nation's leading proficiency testing (PT) services and has substantial experience and expertise in evaluating laboratory performance.

AAB was particularly pleased that Congress passed, and the President signed, the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). At that time AAB believed this statute would ensure that all laboratory testing would be conducted according to certain minimum federal standards.

Unfortunately, the following events have led us to believe that the Administration does not intend to implement this law in a site-neutral manner as required by the statute:

(1) The draft NPRM issued by HCFA includes a large number of tests in the waiver category notwithstanding reports that the Centers for Disease Control (CDC) found few, if any, tests that meet the statutory requirement of having "an insignificant risk of erroneous results" and posing "no reasonable risk of harm to the patient if performed inaccurately;"

Member, Council on the Continuing Education Unit,
National Committee for Clinical Laboratory Standards
and the National Council on Health Laboratory Services.

(2) The comments that the Office of Management and Budget (OMB) submitted to HCFA regarding the CLIA '88 NPRM and references in the FY 1992 Budget indicate that OMB is promoting a reduced standard for physician office laboratory testing; and

(3) HCFA has refused to meet with AAB and other laboratory organizations that have requested assurances from HCFA that the CLIA '88 rules would be issued expeditiously and in a site-neutral manner.

AAB applauds your vigilance and urges you to examine these issues to ensure that CLIA '88 is fully implemented as soon as possible.

We would appreciate your including in the Subcommittee's hearing record AAB's comments to HCFA on the proposed rule and AAB's correspondence with HCFA.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Associate Administrator

rhs

AMERICAN ASSOCIATION OF BIOANALYSTS
Suite 918 • 818 Olive Street • St. Louis, Missouri 63101 • (314) 241-1445

1990-91
BOARD OF DIRECTORS

President
SHIRLEY CRESSWELL, BLD
Professional Laboratory Service
1514 North Michigan Avenue
Saginaw, MI 48602
(517) 771-6830

President-Elect
WILLIAM W. TRIEBER, BLD
Ygnacio Laboratories
120 La Casa Via, Suite 102
Walnut Creek, CA 94598
(415) 939-5344

Vice-Presidents
HAROUTUNE DEKIRMENJIAN, Ph.D., CLD
National Psychopharmacology Lab., Inc.
9320 Parkwest Boulevard
Knoxville, TN 37923
(615) 690-8101

THEODORE J. PASSON, JR., Ph.D., BCLD
Hoyle-Passon Laboratories, Inc.
211 White Horse Pike
Audubon, NJ 08106
(609) 547-8421

Secretary/Treasurer
EDWARD H. EATON, BLD
Claymont Medical Laboratory
1320 Philadelphia Pike
Wilmington, DE 19809
(302) 798-2520

Regional Administrative Secretaries

Midwestern Region
DAVID KOUCHE
Bio-Path Laboratories
36001 Euclid Avenue
Willoughby, OH 44094
(216) 946-3326

Western Region
ELIZABETH T. LOWE, BLM
Allied Medical Laboratories
20392 Town Center Lane
Cupertino, CA 95014
(408) 252-8336

Southern Region
NICHOLAS T. SERAFY, JR.
AAB Proficiency Testing Service
205 West Levee Street
Brownsville, TX 78520
(512) 546-5313

Eastern Region
ROBERT J. KOKOSKI, Ph.D.
Friends Medical Laboratory
5820 Southwestern Boulevard
Southwestern Professional Building
Baltimore, MD 21227
(301) 247-4417

Manager Representative
MARY JANE BURT
Burt Medical Laboratory
126 Sherman Avenue, Box 1655
New Haven, CT 06507
(203) 865-2147

Supervisor Representative
SHAWN J. HARTLEY, BLS
Ballentine & Shub Laboratories
1111 Park Avenue
Baltimore, MD 21201
(301) 523-0043

Section Representative
NICHOLAS T. SERAFY, BLD
AAB Proficiency Testing Service
205 West Levee Street
Brownsville, TX 78520
(512) 546-5313

COMMITTEES

Government & Professional Relations
ALVIN M. SALTON, BLD
Community Medical Laboratories
293 Main Street
Metuchen, NJ 08840
(201) 494-5600

Division of Professional Services
Proficiency Testing Service
NICHOLAS T. SERAFY, BLD, Director

Continuing Education
SHIRLEY CRESSWELL, BLD, Chairman

Constitution & Bylaws
ALVIN M. SALTON, BLD, Chairman

Board of Scientific Advisors
DAVID KOUCHE, Chairman

Administrator
DAVID BIRENBAUM

Associate Administrator
MARK S. BIRENBAUM, Ph.D.

September 19, 1990

Health Care Financing Administration
Dept. of Health and Human Services
Attention: HSQ-176-P
P.O. Box 26676
Baltimore, MD 21207

Dear Sir or Madam:

Herewith are the comments of the American Association of Bioanalysts (AAB) regarding the proposed regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) as published in the May 21, 1990 Federal Register, Vol. 55, No. 98, pages 20896-20958.

AAB, founded in 1956, is a professional association representing directors, owners, managers, and supervisors of community clinical laboratories throughout the United States.

According to the HHS Inspector General[1], by 1987 nearly half of Medicare Part B payments for laboratory services were made to physicians performing tests in physician office laboratories (POLs). That percentage has undoubtedly increased significantly since 1987. AAB sees no reason why POLs and other currently non-regulated facilities should not be required to meet the quality control, proficiency testing, and personnel requirements imposed on non-POL laboratories. AAB therefore strongly endorses the "site-neutral" system of regulation established by CLIA '88.

Member, Council on the Continuing Education Unit,
National Committee for Clinical Laboratory Standards
and the National Council on Health Laboratory Services.

A number of primary care physicians claim that since they interpret test results, laboratory tests performed in POLs do NOT have to meet the same standards as those for non-POL laboratories. A contrary view was expressed by Paul Bachner, M.D., Chairman of the Department of Laboratory Medicine and Pathology at United Hospital in Port Chester, New York, in the January, 1986 issue of The Internist:

> Although lab results must be interpreted in the context of the clinical setting, the integrity of the individual lab result on a given day must be guaranteed by a systematic and reliable program of quality control - one capable of insuring that instruments are properly calibrated and that patient specimens are analyzed in conjunction with control materials of defined analyte composition.

An inaccurate test result, whether produced by a hospital laboratory or a POL, does not contribute to effective medical treatment. It is HCFA's responsibility and mandate under CLIA '88 to establish a regulatory system to improve the quality of laboratory testing performed in all settings.

In addition, the proposed rules have upset many manufacturers/providers of POL laboratory equipment and supplies. It is understood that these manufacturers have a vested financial interest in the laboratory market and in the development of testing systems. But CLIA '88 has a single objective, which is to provide competent clinical laboratory service to the public. If, in the process of reaching this objective, there is an adverse financial impact upon the suppliers of laboratory hard and soft goods, we can be sympathetic, but not concede that such a factor is in any way determinative of the provisions of statute and regulations.

AAB therefore urges HCFA to proceed promptly in implementing a final rule based, we hope, on the suggestions provided in these comments.

Section 493.15 Laboratories performing certificate of waiver tests

All laboratory tests worth performing carry some risk of harm to the patient if done incorrectly, and as far as we know, no laboratory test has a negligible likelihood of an erroneous result. "Simple" urine dipstick tests can yield erroneous results if the reagent strips are outdated or exposed to excess heat and humidity. An incorrect urine "dipstick" test for glucose, protein, or ketone could most certainly create the potential for harm to the patient. For example, a false negative protein result could mask serious kidney disease.

AAB recommends that tests in the Waivered category be limited to those which have been approved by the Food and Drug Administration (FDA) for home use. Our reason for permitting FDA home test kits to be waivered is not based on a belief that FDA approval implies that these tests are foolproof. In fact, there may be risks associated with these kits. However, Congress specifically "waivered" these home test kits in the CLIA '88 statute.

Section 493.3 Applicability

AAB shares HCFA's concern that it may be difficult to prevent physicians from using emergency test authorization to bypass regulatory requirements.

The purpose of this proposed rule is to "improve health care by increasing the accuracy of test results, reducing both false negative and false positive results, and limiting or reducing the numbers of erroneous or incorrect laboratory test results that cause patient morbidity and mortality, more expensive care and drug regimen."

Standards should not be compromised in emergency situations. An inaccurate laboratory test result will not aid the physician in providing emergency care. If these standards are necessary, then they should be applied in all situations, including emergency care.

Section 493.20 Laboratories performing Level I tests
Section 493.25 Laboratories performing Level II tests
Section 493.30 Categorization of certificate of waiver, Level I and Level II tests

The decision to categorize tests into Waivered, Level I, and Level II categories is fraught with complications and difficulties. In so doing, a never-ending battle over how to categorize tests will ensue. For example, some manufacturers want HCFA to categorize tests based solely on the test methodology rather than HCFA's approach of categorizing by "analyte", which encompasses a number of factors (including methodology). Furthermore, under this tiered system, members of the Technical Advisory Panel (TAP) will come under extreme pressure from various groups which may affect their ability to properly protect the well being of the patient public.

Therefore, AAB proposes that HCFA eliminate these problems by establishing only one level of tests other than "Waivered". Therefore, Section 493.20 should be deleted.

Since the proposed rules for Level I and Level II tests differ only in the area of personnel requirements, it is these differences which must be resolved. (This is not to say that all of the proposed rules in the other areas are acceptable; it is just that changes made there will affect Level I and Level II tests in the same manner).

It is our firm belief, based on the many years of experience of AAB members and publications by laboratory regulatory agency officials[2,3,4,5], that the training, knowledge, and skill of the individual performing the test procedure is directly related to the accuracy and reliability of test results.

AAB recognizes that in some disciplines the technical performance of a test procedure has been made simpler by advances in technology and instrumentation. However, the fact that a test procedure is simple to perform does not guarantee that the results will be accurate and reliable.

Some manufacturers have suggested that the 510K process of the FDA be used to classify instruments into the "Waivered" category. AAB believes that the FDA 510K process does not adequately address the concerns about quality control embodied in CLIA '88. FDA does not evaluate instruments based on data obtained from its own independent analyses. Rather, FDA relies on manufacturer supplied data which are usually produced under controlled circumstances utilizing trained laboratorians. In order to evaluate instruments for "waivered" status, HCFA would have to conduct its own independent field tests in which non-laboratorians operate the instruments or kits.

More importantly, many errors are made in the pre-analytical stage of testing (including patient preparation; specimen preparation, collection, handling, storage, and labeling; reagent or test strip storage, including exposure to heat and humidity; instrument calibration and maintenance) and the post-analytical stage of testing (including documentation and reporting of results; analysis of quality control results; computations; consideration of interfering substances and instrument bias). Many of these sources of error cannot be eliminated by simplifying the analytical instrument or test kit.

AAB proposes that all individuals providing clinical laboratory testing be required to demonstrate their ability to properly perform laboratory procedures.

AAB encourages HCFA to establish personnel regulations which are flexible, encourage career advancement and mobility, and which recognize laboratory knowledge and skills acquired in a variety of settings. Having the skills and knowledge to perform competently on-the-job is the paramount issue, not where or how those skills are obtained.

We strongly encourage HCFA to utilize proficiency examinations as one of the routes for meeting personnel requirements. AAB also urges HCFA to continue offering the HHS Proficiency Examination for medical technologists, especially since these proposed rules recognize the HHS Proficiency Examination as a qualification for meeting the requirements for technologist and supervisor.

Subpart C Provisional Certificate and Certificate
Sections 493.43 and 493.53

If the number of CLIA regulated testing sites is substantial, we propose that HCFA adopt the recommendation of the Association of State and Territorial Public Health Laboratory Directors that laboratories be subject to inspection based on a random selection of 10-15% of laboratories each year (in addition to laboratories which experience consistently poor performance on proficiency testing or for which there is evidence that performance is substandard).

Subpart H and Subpart I

Sections 493.801 - 493.959 Proficiency Testing Requirements

AAB has offered a full service proficiency testing program since 1949. AAB's Proficiency Testing Service is an approved proficiency testing program for laboratories certified by Medicare, licensed by CLIA '67, and licensed or regulated by state law (the only exception being New York which operates its own state proficiency testing program).

Amended to these comments as Exhibit 1 are AAB's recommendations for improving the proposed rules governing proficiency testing contained in Sections 493.801 - 493.959.

Section 493.1101 Condition: Patient test management; Level I and Level II testing

Paragraph (a) sets forth standards for specimen submission. While the laboratory must make available to clients written instructions for specimen collection, there are no requirements which must be met when the specimen is procured in a non-laboratory setting.

Senators Brock Adams and Barbara Mikulski testified at Senate hearings held before passage of CLIA '88 that half of the errors in Pap smear testing occur in the doctor's office during collection of the specimen. Requiring laboratories to police the proper collection of specimens will not work. Many physicians will not accept a laboratory's determination that they (the physician) have erred during the specimen collection process, and many laboratories are reluctant to return specimens because of fears of losing the physician's referrals.

We urge HCFA to adopt standards (similar to those proposed in Section 493.1101) for specimen collection which are applicable in all settings, including those in a non-laboratory facility.

Section 493.1203 Standard; Facilities

Identifying power surges is costly and difficult. Monitoring electrical power variances should be limited to special situations, such as for blood bank refrigerators or computer systems requiring documentation of system shutdown and start-up.

Instead of requiring identification and documentation of electrical power variances, AAB recommends requiring the use of Uninterrupted Power Sources (UPS) for essential electrical instrumentation.

Section 493.1207 Standard; Temperature and humidity monitoring

In some locales, maintaining laboratory humidities within acceptable ranges is next to impossible.

Instead, AAB recommends requiring that specimens, tissue, reagents, and supplies be stored in rooms or containers meeting manufacturer specifications for temperature and humidity.

Section 493.1217 Standard; Frequency of quality control

The frequency of quality control as established in Appendix C of the State Operations Manual should have been published with this proposed rule. Since it was not, we have great difficulty in commenting on its appropriateness.

Utilizing the State Operations Manual for the purpose of establishing the frequency of quality control is inappropriate unless changes in the State Operations Manual are made according to the Administrative Procedures Act, including providing proper notice and allowing public review and comment.

Section 493.1405 Standard; Laboratory Director qualifications (for Level I Laboratories)

Since AAB proposes combining Level I and Level II into one category, section 493.1405 should be deleted.

It is clearly inappropriate to permit a physician with no laboratory training or experience to direct a laboratory. Many physicians do not receive clinical laboratory training in medical school or in their internship and residency. Recent evidence (Exhibit 2) published in the July 18, 1990 issue of the Journal of the American Medical Association (Vol. 264, No. 3, pp. 382-386) demonstrates that physician residents lack the ability to properly perform a number of "simple" laboratory procedures, including some that HCFA proposes to place in a "Waivered" or "Level I" category. We quote the authors of this study, Lee H. Hilborne, M.D., Neil S. Wenger, M.D., and Robert K. Oye, M.D.:

> Laboratory tests by primary care physicians are an integral part of many medical practices, yet there is little formal education in laboratory methods in medical school and rarely any in post-graduate training.... In an era of growing emphasis on quality of care, physicians who perform laboratory procedures must demonstrate their competence to do so.
>
> This study shows that many house officers at one institution may not perform all laboratory tests with the analytic precision necessary to provide optimal patient care.

Section 493.1415 Standard; Laboratory director qualifications

When establishing personnel regulations, prime consideration should be given to who performs the functions of each level, rather than who has traditionally been afforded the title.

There are too many "paper" directors and technical supervisors under the current Medicare/CLIA '67 regulations. In many cases, it is the chief supervisor or chief technologist who functions as the director. AAB therefore strongly urges HCFA to permit these individuals to be recognized for the job they are already doing.

The essence of graduate degrees is the ability to conduct independent research. This ability is essential for the advancement of basic and applied laboratory sciences, but it is not required for the provision of most clinical laboratory services. A well rounded curriculum in the basic laboratory sciences, together with practical on-the-job experience, is sufficient to allow individuals to function as directors and technical supervisors. AAB recommends that the minimum educational requirement for director and technical supervisor be a baccalaureate degree (or equivalent) with a major in an appropriate biological, chemical, or physical science.

Other AAB Recommendations:

paragraph (1)(iv):	Delete "Subsequent to graduation". Add paragraph (1)(v): "or, pass a proficiency examination approved by the Department of Health and Human Services."
paragraph (4):	Change "doctoral" degree to "baccalaureate" degree.
paragraph (4)(ii):	Delete "Subsequent to graduation". Add "four (4) years (doctoral degree) five (5) years (masters degree) or six (6) years (baccalaureate) degree of full-time general laboratory training and experience...."

Section 493.1421 Standard; Technical Supervisor qualifications

(b)(2)(i)	Add: "or baccalaureate degree".
(b)(2)(ii)	Delete: "Subsequent to graduation".
Add (b)(2)(iii):	"or, is certified in the laboratory specialty of microbiology by the American Board of Medical Microbiology, the American Board of Bioanalysis or other national certifying board acceptable to HHS;"
Add (b)(2)(iv):	"or, passes a proficiency examination in the specialty of Microbiology approved by HHS."
(c)(2)(i)	Add: "or baccalaureate degree".

(c)(2)(ii)	Delete: "Subsequent to graduation".
Add (c)(2)(iii):	"or, is certified in the laboratory specialty of immunology by the American Board of Medical Microbiology, the American Board of Bioanalysis, or other national certifying board acceptable to HHS;"
Add (c)(2)(iv):	"or, passes a proficiency examination in the specialty of immunology approved by HHS."
(d)(2)(i)	Add: "or baccalaureate degree".
(d)(2)(ii)	Delete: "Subsequent to graduation".
Add (d)(2)(iii):	"or, is certified in the laboratory specialty of chemistry by the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national certifying board acceptable to HHS;"
Add (d)(2)(iv):	"or, passes a proficiency examination in the specialty of chemistry approved by HHS."
(e)(2)(ii)	Delete: "Subsequent to graduation".
Add (e)(2)(iii):	"or, is certified in the laboratory specialty of hematology by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national certifying board acceptable to HHS;"
Add (e)(2)(iv):	"or, passes a proficiency examination in the specialty of hematology approved by HHS."
(i)(2)(ii)	Delete: "Subsequent to graduation".
Add (i)(2)(iii):	"or, is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national certifying board acceptable to HHS;"
Add (i)(2)(iv):	"or, passes a proficiency examination in the specialty of radiobioassay approved by HHS."
(l)(3)	Delete: "subsequent to graduation".
Add (l)(3)(i):	"or, is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national certifying board acceptable to HHS;"

Add (1)(3)(ii): "or, passes a proficiency examination in the specialty of immunohematology approved by HHS."

Section 493.1427 Standard; General Supervisor qualifications

Individuals trained in a variety of settings (other than a four year college or university) can competently perform the duties of a technologist and general supervisor. HCFA has acknowledged this by proposing that individuals who passed the HHS Proficiency Examination for medical technologists be permitted to qualify as technologists and general supervisors (with 3 years subsequent experience).

The proposed regulations provide an alternate route for individuals who do not have a baccalaureate degree to qualify as technologist and supervisor. However, as a practical matter, the Department of Health and Human Services is no longer offering the Proficiency Examination for medical technologists.

In order for these proposed regulations to contain a meaningful alternate route for qualified bench personnel, it is imperative that the HHS Proficiency Examination be reinstated and offered on a regular basis.

Section 353(f)(1)(C) of Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988, provides ample authority for the Secretary to once again administer such an examination.

Add (4)(iii): "or is certified by the American Board of Bioanalysis or other national certifying board acceptable to HHS."

Section 493.1433 Standard; Technologists qualifications

In paragraph (a), change: ";and" to ";or"

This change permits state licenses for medical technologists to be recognized in those cases where a technologist does not meet the qualifications listed in paragraph (b).

Add: "(c) or, qualified under state law as a technologist."

Many states establish personnel requirements for technologists through a facility licensure system rather than personnel licensure. Recognizing individuals who meet these state requirements will reduce confusion and increase career mobility.

Section 493.1441 Standard; Technician qualifications

Add (7): "or, passes a proficiency examination approved by HHS."

Section 493.1442 Standard; Personnel qualifications for test performance

Obtaining the necessary experience to qualify as a technician needs clarification. In order to perform Level II testing designated in paragraph (b) the technician must have six (6) months - one (1) year of experience. How is this individual to gain the experience? Presumably, paragraph (c) permits individuals meeting the qualification listed in Section 493.1441 to perform Level II tests if supervised by a technologist. If so, we suggest adding a clarifying sentence as follows:

> Individuals meeting the qualifications listed in Section 493.1441 may gain the necessary experience to qualify to perform Level II tests listed in Section 493.1442 (b) by working in a Level II laboratory under the direct supervision of an individual qualified as a technologist under Section 493.1433. During this time the individual's status will be referred to as "provisional" technician.

It is inconsistent to require work experience for Level II tests performed by technicians as listed in paragraph (b) but not require work experience for Level II tests requiring a technologist as listed in paragraph (a). This is especially true since performing many of the tests listed in paragraph (a) require subjective qualitative determinations.

AAB suggests adding a minimum of one (1) year work experience to the tests listed in paragraph (a). Alternatively, individuals could be required to pass a practical examination in these disciplines.

Submitted by,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Associate Administrator

Footnotes

1. "Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests" HHS Office of Inspector General, Office of Audit. CIN: A-09-89-00031 (Revised); January 24, 1990.

2. Naughton, M.J., Luepker, R.V., Strickland, D. "The accuracy of portable cholesterol analyzers in public screening programs." JAMA. 1990; 263:1213-1217.

3. Nanji, A.A., Poon, R., Hinberg, I. "Desktop analysers: quality of results obtained by medical personnel." Canadian Medical Association Journal. March 15, 1988; 138:517-520

4. Belsey, R., Goitein, R.K., Baer, D.M. "Evaluation of a laboratory system intended for use in physician's offices. I. Reliability of results produced by trained laboratory technologists." JAMA. 1987; 258-353.

5. Belsey, R., Vanderbark, M., Goiten, R.K., et.al. "Evaluation of a laboratory system intended for use in physician's offices. II. Reliability of results produced by health care workers without formal or professional laboratory training." JAMA. 1987; 258:357.

Exhibit 1

COMMENTS by the
AMERICAN ASSOCIATION of BIOANALYSTS
on PROPOSED PROFICIENCY TESTING REGULATIONS

AAB supports the goal of these proposed rules, that is, to implement Public Law 100-578 (CLIA '88) such that the accuracy of laboratory testing is improved. However, the proposed rules fall short of this goal in the following essential aspects:

I. Peer method grading (method-specific target values) the linchpin without which the wheel of proficiency testing slides irretrievably off the axle of clinical relevancy - is omitted.

II. Subspecialty scoring - it is unconscionable to base failure for a subspecialty on failures for a single analyte within the subspecialty, especially when such drastically different failure rates (0.27 - 70%) occur for different analytes using the proposed grading limits.

III. Grading suspensions - continued mandates for the PT providers - both to default grading to comparable groups when some groups would otherwise be ungradable and to count as passing responses those which have no comparable group to which to default - are omitted.

Following is a detailed analysis, with recommendations, for improving the proposed rules.

I. Peer Group Grading.

A. The Proposed Rule language most cataclysmic to proficiency testing as we know it today is the definition of target value in paragraph 493.2 which indicates grading on the basis of only one target value per analyte. For example, using this definition, AST(SGOT) would have had a 47% failure rate and bilirubin a 53% failure rate on our 2nd quarter, 1990 survey, whereas with appropriate peer grouping the rates would generally be less than 10%. When the consequences of such high failure rates are compounded by the practice of basing the suspension of testing for an entire subdiscipline on failed performance for any analyte, one should readily comprehend the validity of our applying the word "cataclysmic" above to the prospects of grading responses under the Proposed Rules.

B. Peer group grading is based on the premise that knowledge of the source of errors is far more important than mere detection of their existence:

1. The type of analytical error, random (variation) versus systematic (bias) cannot be distinguished without peer grouping.

2. It is extremely important that participants and PT providers alike be able to know that grading is independent of sample-specific factors. And it is a far more safe and cost-effective approach to eliminate all sample-specific bias from the grading process by using peer group grading than to try to anticipate, identify and control all the sample-specific factors which might render single target value grading inappropriate.

C. Peer group grading avoids the appearance of endorsing commercial products whose responses happen to coincide with single target values which inevitably mislead participants since the specific products to which participants' attention are drawn change from sample to sample, even when samples display similar target values.

D. One fundamental reality of analysis is ignored by single target grading: since no analytic method is 100% specific, different methods never measure identical constituent(s). For example, the response of "hCG" methods may represent a continuum of combinations of responses to at least two different forms of B-hCG molecules, not a simple one-to-one response to any specific form of B-hCG. This fact may be why the Proposed Rules retain statistical grading limits for most hormones, guaranteeing a passing grade for 99.73% (3SD) of all responses (assuming a normal distribution of responses). Nevertheless, consider for a moment the analyte with the most tightly controlled fixed grading limits (less than 3%): sodium. How close do its methods approach the analytical ideal of identical constituent responses? Not very close, else we would not always ask when presented with sodium measurements, "do these results represent sodium concentration or sodium ion activity?" For years we have documented spreads of means between these two types of methods which exceed the proposed grading limit for sodium (4 mmol/L)!

E. In short, peer grading relieves participants of many adverse effects which are caused by factors beyond their control while retaining much more information which they can use to provide better patient care without impeding the continued progression of innovative methods available from the private sector.

F. Grading by peer group target values is so entrenched in proficiency testing today that authors of the Proposed Rules may have thought their use implicit in the language used. However, much of the concern which prompts comments to these Rules could be allayed with the following two short changes in the language of paragraph 493.2:

1. Replace
   "Target value means either the mean of all responses"
   with
   "Target value means either the mean of responses of a methodologically homogeneous group".

2. After "In instances where",
   insert "method-specific group means or".

II. Subspecialty Sanctions.

A. We continue to be appalled that the Health Care Financing Administration (HCFA) retains single analyte-based subspecialty sanctions with at least four such clear outcomes:

1. The risk of sanctioning a laboratory for a given subspecialty is a direct function of the number of analytes reported, assuming comparable restrictiveness of their grading limits. For example, if each analyte has a probability of being sanctioned in 1% of all testing events, a laboratory only reporting one analyte has a zero probability of being sanctioned for any analytes except the one being reported, but a laboratory doing 5 analytes has a probability of being sanctioned for all 5 analytes in 5% of all testing events, and a laboratory doing 25 analytes has a probability of being sanctioned for all 25 analytes in 25% of all testing events!

2. The risk of subspecialty sanctions is therefore also a direct function of the size of the subspecialty's regulated analyte list, that is, the larger HCFA's subspecialty menu of analytes, the more likely the subspecialty will be sanctioned, assuming comparable proportions of analytes reported and comparable restrictiveness of the limits imposed on these analytes. For example, if analytes of both subspecialties have comparable probabilities of being sanctioned, a laboratory is three times as likely to be sanctioned in the Routine Chemistry subspecialty (with 27 analytes) than in the subspecialty of Endocrinology (with only 9 analytes), assuming the same proportion of analytes are reported.

3. The risk of subspecialty sanctions is also a very strong function of the criticality of care supported by the lab for at least two reasons:

a. A laboratory supporting critical patient care generally offers a larger test menu and therefore exposes itself to a higher risk of sanctions.

b. The analytes essential to the support of critical care (such as electrolytes and blood cell counts) have far higher failure rates under than the Proposed Rules than analytes not routinely used in acute care settings (such as hormones and immunoglobulins).

Can HCFA seriously retain a system which sanctions labs with a frequency directly related to the criticality of the patient care settings they support?

4. The single analyte-based subspecialty sanctions being retained do not penalize the laboratory which fails only one analyte in the subspecialty any less than the one which fails all analytes!

B. All of the objections to single analyte-based subspecialty sanctions have the obvious remedy of changing sanctions to an all-analyte basis. Already in place are subspecialty sanctions based on average analyte subspecialty scores. If there is a need for subspecialty sanctions on an additional basis, it should also reflect performance on all analytes in the subspecialty.

C. Paragraph (f) of the following sections of Part 493 must therefore be deleted from the Proposed Rules: 835, 837, 841, 843, 845, 851, 859 and 865.

III. Grading Suspensions.

A. In our experience the potential number of sources of sample-specific discrepancies which could inappropriately affect participant results are too numerous to summarize comprehensively here. Instead, we will outline our general approach to the issue of sample integrity/method compatibility in order to give some indication of the complexities involved in supplying gradable PT materials:

1. We develop and/or acquire samples which represent the cutting edge of control sample technology. For example, one of the new products we were the first in the clinical laboratory industry to introduce was a human whole blood sample for blood glucose meters and we continue to hone the properties of this material every quarter such that the meter-to-meter variation in target value is minimized.

2. We continually identify and enlist the help of individuals in the employ of clinical laboratory product manufacturers who are willing to assist us in prospectively anticipating and preventing and retrospectively identifying and evaluating various issues of compatibility between our samples and their products. For example, we make a minimum of eight mailings annually to keep our nearly one hundred industry contacts well informed of our operations. We collaborate with dozens of these and other industry personnel on various sample problems on an ongoing basis.

3. In addition, we provide 800 service for participants to report discrepancies they may detect. This serves as a prime information source, further enhancing our efforts to detect sample problems prior to grading results.

4. Nevertheless, each quarter we routinely screen over twenty thousand potential peer method groups for exceptional data in order to detect sample issues unnoticed by participants and vendors alike.

5. Finally, every factor we find in our samples translates into a revised protocol at some level in our operations - from the sample formulation level to the graded report level.

B. In spite of our sample monitoring system, or more accurately, because of it, there are well defined circumstances under which we must have the flexibility to suspend grading, whether or not a resolution of the problem is forthcoming:

1. Method-nonspecific sample issues. If too many of our hematology samples, for example, become frozen in transit during a major cold wave such that our replacement stock is exhausted, we obviously must have a mandate to either suspend grading on participants whose samples could not be replaced or suspend grading altogether (probably the fairer of the two alternatives, considering the number of participants who might be unaware of the problem and do not request replacements, yet whose results are nevertheless marginally affected).

2. Method-specific sample issues occur in two different forms which may require grading suspensions:

a. Statistically defensible method groups. This type becomes an issue only if peer group grading is forbidden. Since whole blood samples are required for hematology, for example, there are large discrepancies in the response dry chemistry analyzers will give for hemoglobin in this material. Again, as long as peer group grading is allowed, this will not, however, present a need for withholding grading of PT samples.

b. Statistically indefensible method groups. Extending the example just given of hemoglobin results from dry chemistry analyzers, several particular instruments may consistently show a bias which makes them incomparable to any other method for default grading purposes, yet the PT provider does not have a sufficient statistical basis for peer grading. The PT providers must continue to have the mandate they have enjoyed in the past, namely, the freedom to suspend grading on this basis.

C. Historically, Medicare surveyors sanction laboratories more severely for failing to report results than for reporting unacceptable results. Indeed, unreported results count as automatic failures in their computation of overall scores. This practice is not changed under the Proposed Rules. However, the added incentive historically given to participants to report results they might otherwise omit - that of counting ungraded results as passing performance in computing overall scores - is not specified in the Proposed Rules. Not only is treating ungraded results as passing performance an important practice for ensuring maximum participation in proficiency testing, but also this practice is important to fulfill the rationale for mandating five challenges per testing event under the Proposed Rules - a laboratory may miss one sample per analyte per testing event without being sanctioned for that analyte. This crucial aspect of the entire system of scoring and sanctions in the Proposed Rules is destroyed if ungraded results are treated as other than passing performance.

D. To remedy these omissions only short clarification in the language of the Proposed Rules is required in the definition of target value in paragraph 493.2:

> After "that such an evaluation is not appropriate" insert ", in which case the target value is undefined and all responses may be considered acceptable.".

HOMECARE™

NATIONAL ASSOCIATION FOR HOME CARE
519 C STREET, N.E., STANTON PARK
WASHINGTON, D.C. 20002-5809
Telephone: (202) 547-7424, FAX: (202) 547-3540

ANNE M. KATTERHAGEN
CHAIRMAN OF THE BOARD

VAL J. HALAMANDARIS
PRESIDENT

HONORABLE FRANK E. MOSS
SENIOR COUNSEL

STANLEY M. BRAND
GENERAL COUNSEL

May 13, 1991

John D. Dingell, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2323 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

The National Association for Home Care (NAHC) respectfully requests the opportunity to testify before the Subcommittee on Oversight and Investigations on any future hearings relating to the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

NAHC represents approximately 6,000 home health agencies, homemaker-home health aide organizations and hospices. As proposed, the CLIA '88 regulations would classify a broad range of facilities as "laboratories" and would require that these facilities comply with complex and costly regulations except where the facility provides only specified tests which the Department of Health and Human Services (HHS) has classified as "waivered" tests. NAHC and its members believe that the regulations exceed Congressional intent and the authority of the statute with regard to the types of providers which the Health Care Financing Administration (HCFA) proposes to include under regulation.

Thank you for your consideration.

Kindest regards

Sincerely,

Val

Val J. Halamandaris
President

VJH/eb
Enclosure

NATIONAL ASSOCIATION FOR HOME CARE
Statement for the Record
on the

Clinical Laboratory Improvement Amendments of 1988

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

U.S. House of Representatives
Washington, D.C.

May 2, 1991

****

The National Association for Home Care (NAHC) is the nation's largest professional organization representing nearly 6,000 home care providers and hospices throughout the country. On behalf of our members and the patients whom they serve, we wish to express our concerns regarding the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

As proposed, the CLIA '88 regulations would classify a broad range of facilities as "laboratories" and would require that these facilities comply with complex and costly regulations except where the facility provides only specified tests which HHS has classified as "waivered" tests.

Statutory Authority

After review of the statute, legislative history and proposed regulations, NAHC believes that the regulations exceed the intent of Congress and the authority of the statute with regard to the types of providers which the Health Care Financing Administration (HCFA) proposes to include under the regulations.

NAHC believes that the Clinical Laboratory Improvement Act does not apply to home care agencies. Under CLIA, a laboratory is a facility for the "examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" (emphasis added).

First, a home health agency is not a facility. No reference is made in the statutory language or the legislative history which indicates that a home health agency that tests a patient's specimen and obtains a test result within the patient's home is considered a facility subject to CLIA.

Second, CLIA applies to facilities providing testing of multiple "human beings" in a single site. The risks of specimen mismanagement occurring in a multiple-patient setting are not present in home health care where a single patient is tested.

Finally, if CLIA extends to home health agencies, it must also extend to the patients themselves. A parent of a hypoglycemic child who uses a glucometer to test blood sugar levels presents a circumstance that is on a par with home health agency nurses performing the same test. Clearly, Congress did not intend to regulate the patients in the home setting, and we believe that Congress also did not intend that home care providers offering the same services be subject to the regulations.

Waiver of Additional Tests

If, notwithstanding these considerations, it is determined that the statute does provide the authority to regulate home care providers, we feel that the waiver provisions of 42 USCS 263a(d)(2) justify the waiver of additional tests. The statute specifies the following:

> "In general. A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver reviewed..."

And 42 USCS 263a(d)(3) specifies:

> "The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which--
> (A) have been approved by the Food and Drug Administration (FDA) for home use,
> (B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or,
> (C) the Secretary has determined the tests pose no reasonable risk of harm to the patient if performed incorrectly."

The proposed regulations list a number of tests which may provide a basis for granting a certificate of waiver. Based on the statutory language, NAHC believes that this list of "waivered" tests should be expanded to include the following routine tests which are frequently performed in the course of home care visits.

(1) Glucose Testing

NAHC believes that capillary blood testing for glucose using reflectance meters should be classifed as a waivered test. FDA has approved the glucose testing instruments for home use, and an estimated 1 million diabetics are currently using the equipment.

The statute clearly indicates an intent that tests which FDA has approved for home use be waivered. However, HCFA has created an artificial distinction between the types of FDA approval which appears to recognize the FDA premarket approval (PMA) but not the FDA's 510(k) approval for over-the-counter sale of the instruments for home use. Nothing in the statute supports a distinction between the types of FDA approval. It is unreasonable to require a provider to be a fully certified laboratory to offer a test which a patient can purchase "over-the-counter" and use with minimal, if any, training. Therefore, the existence of FDA approval rather than the type of approval should be the basis for classifying the test.

The equipment and procedures for administering these tests also satisfy the simplicity criterion of the statute. They require a minimum of calibration, calculation and judgement. HCFA itself has classified home glucose testing in home care settings as a non-skilled service which does not require a licensed nurse. It is inconsistent for HCFA to define the same test as a "non-skilled" home health service while at the same time mandating that only a skilled, certified laboratory can perform the test. NAHC therefore feels that HCFA should reclassify these tests as waivered tests in accordance with the statutory provisions.

(2) Screening Tests

NAHC also believes that hemoglobin, hematocrit and cholesterol tests fall within the statutory provisions for waivered tests and should be reclassified as such.

These screening tests are simple procedures and inaccurate results pose no reasonable risk of harm to patients. They are used in conjunction with interviews and other observations to identify patients who need further testing or assessments. They do not serve as the basis for a diagnosis or for the initiation or modification of treatment. Therefore, the risk to the patient as a result of such testing is minimal.

Existing Regulations

We note that the proposed regulations would duplicate quality assurance programs which are already in place and which are better suited to the home care setting. At the very least, we believe that home care providers that are certified by Medicare, licensed by their state or accredited should be deemed to have met the CLIA regulations. These programs are specifically tailored to home care services and circumstances and are both more appropriate and more effective in assuring quality of care than the proposed CLIA regulations. Medicare certification, state licensure regulations and accreditation standards for home health agencies already include requirements for the qualifications and training of staff performing services in the home, patient care policies and procedures, adherence to professional standards, and recordkeeping. These quality assurance programs also involve direct observation of clinical services as well as review of policies and procedures.

User Fee Schedule

The regulations propose to charge a user fee for the issuance of both laboratory certificates and waiver certificates. NAHC feels that it is inappropriate to require payment for what is in effect a pro forma review of an agency's statement that it is not performing tests which are subject to the regulations. Imposing a fee on waivered providers would inappropriately increase the costs of providers to whom the regulations do not apply, and in the case of home health agencies, would result in increased costs to the Medicare program through inclusion of the user fee in the cost report. We therefore recommend that no fee be charged where a waiver certificate is granted.

Additional Comments: Regulatory Impact

NAHC feels that the application of the proposed CLIA regulations to home care providers and hospices and to the tests indicated earlier in this document is not only contrary to the language of the statute, it would also increase costs and reduce availability of the tests.

Home health agencies and hospices are not currently separately reimbursed by Medicare or other third party payors for the tests performed in the home. These tests are provided incidental to teaching or other skilled services. Therefore, many home care providers will discontinue home testing rather than incur the costs of compliance with the proposed regulations. This would reduce availability of the tests for patients, especially the homebound elderly population who are unable to leave home to obtain tests elsewhere.

Instead of providing the simple home tests, it will be necessary for agencies to draw blood and take it to a laboratory for testing. This will increase the costs of home visits, add additional costs for the laboratory tests for Medicare and other payors, delay the availability of test results and subject patients to the more painful venipuncture procedure rather than simple capillary blood testing.

Agencies which choose to seek laboratory certification would be subject to requirements which are inappropriate for home care providers and which unnecessarily increase costs. For example, the requirement for a physician director for testing in home care settings would increase costs without contributing to improved quality. The few simple tests which home health agencies would perform are those which nurses customarily perform, not those common to laboratory settings. A physician would often be less experienced in the administration of these tests (e.g., blood glucose testing by reflectance meter) than the nurses the physician is expected to train and monitor. In addition, the physician would seldom be in a position to evaluate the performance of tests done in the home. Therefore, the functions of the physician director would be essentially pro forma and the costs in these circumstances would be "featherbedding."

Conclusion

NAHC strongly recommends a careful scrutinization by Congress to assure its intent is being carried out with regard to the implemention of CLIA '88. Should HCFA maintain its current position on the range of providers and tests to be regulated, NAHC recommends that HCFA utilize the existing home health and hospice quality assurance mechanisms to monitor the quality of home testing rather than creating additional duplicative and inappropriate regulations for these entities.

NAHC appreciates the opportunity to comment on the implementation of the Clinical Laboratory Improvement Amendments of 1988.

○

CMS LIBRARY
3 8095 00012647 0

ISBN 0-16-037353-0
90000
9 780160 373534